IBCSG

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Country: Europe, America, Australia, Africa, Asia

Group: International Breast Cancer Study Group **(IBCSG)**

Foundation Council Chair:
B. Thürlimann
Senologie-Zentrum Ostschweiz
Kantonsspital
CH-9007 ST GALLEN
SWITZERLAND
Tel: +41 71 494 20 65
Fax: +41 71 494 63 68
Email: beat.thuerlimann@kssg.ch

Scientific Committee Chair:
A. Goldhirsch
IOSI, Oncology Institute of Southern Switzerland
c/o Ospedale Italiano
Via Capelli
CH-6962 VIGANELLO-LUGANO
SWITZERLAND
and
Department of Medicine
European Institute of Oncology
I-20141 MILANO
ITALY
Tel: +41 91 811 79 23
Fax: +41 91 811 79 25
Email: aron.goldhirsch@ibcsg.org

A. Coates
40 Cook RD
Centennial Park, NSW 2021
AUSTRALIA
Tel: +61 2 9331 3521
Fax: N/A.
Email: alan@ronaonline.net

Chief Executive Officer:
M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Coordinating Center:

A. Hiltbrunner
Executive Director
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: anita.hiltbrunner@ibcsg.org

R. Studer
Head Trial Coordination
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9392
Email: regula.studer@ibcsg.org

Statistical and Data Management Center Director:

R.D. Gelber
IBCSG Statistical Center
Dana-Farber Cancer Institute
44 Binney St.
BOSTON, MA 02115
USA
Tel: +1 617 632 3603
Fax: +1 617 632 2444
Email: gelber@jimmy.harvard.edu

L. Blacher
Director of Data Management
Frontier Science & Technology
Research Foundation
4033 Maple Road
AMHERST, NY 14226
USA
Tel: +1 716 834 0900
Fax: +1 716 836 6097
Email: blacher.lynette@fstrf.org

Quality of Life Office Responsible Person:

K. Ribi
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9229
Email: karin.ribi@ibcsg.org

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Pathology Center Responsible Person:
G. Viale
European Institute of Oncology (EIO)
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 5748 9420
Fax: +39 02 5748 9417
Email: giuseppe.viale@ieo.it

B.A. Gusterson
University of Glasgow
Western Infirmary
Royal Cancer Hospital
The Haddow Hospital
15 Cotswold Road
GLASGOW G11 6NT
UNITED KINGDOM
Tel: +44 141 211 2233
Fax: +44 141 337 2494
Email: b.a.gusterson@clinmed.gla.ac.uk

Website:
www.ibcsg.org

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title:

CMF with or without prednisone for pre/perimenopausal patients with breast cancer and 1–3 positive nodes.
Ludwig/IBCSG Trial I

CMF + prednisone combined with or without oophorectomy for pre/perimenopausal patients with breast cancer and 4 or more positive nodes
Ludwig/IBCSG Trial II

Adjuvant therapy for postmenopausal elderly patients (older than 65): observation *versus* prednisone + tamoxifen.
Ludwig/IBCSG Trial III

Adjuvant therapy for postmenopausal, 65 years or younger, node-positive breast cancer patients: observation *versus* prednisone + tamoxifen *versus* CMF + prednisone + tamoxifen.
Ludwig/IBCSG Trial IV

Coordinator(s):

A. Goldhirsch
IOSI, Oncology Institute of Southern Switzerland
c/o Ospedale Italiano
Via Capelli
CH-6962 VIGANELLO-LUGANO
SWITZERLAND
and
Department of Medicine
European Institute of Oncology
I-20141 Milano
ITALY
Tel: +41 91 811 79 23
Fax: +41 91 811 79 25
Email: aron.goldhirsch@ibcsg.org

Summary:

- Closed in September 1981 (opened in 1978)
- Final accrual for Trials I–IV: 1713 patients

Objectives:

To determine whether we can increase the tumor-free interval or increase survival by combining hormone therapy and cytotoxic chemotherapy when comparing:

- CMF plus prednisone (CMFp) *versus* CMF alone for relatively good prognosis pre- and perimenopausal (1–3 positive nodes) patients.
- CMFp plus oophorectomy *versus* CMFp for poor prognosis (>4 positive nodes) pre- and perimenopausal patients.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

- CMFp plus Tam, *versus* Tam and prednisone, *versus* no adjuvant therapy for postmenopausal patients (N+) up to the age of 65.
- Tam plus prednisone *versus* no adjuvant therapy for postmenopausal (N+) women 66 years and over.

Scheme:

Trial	Group	Treatment
I	Pre- and perimenopausal 1–3 N+	R → CMF / CMFp
II	Pre- and perimenopausal >4 N+	R → CMFp / Ox → CMFp
III	Postmenopausal N+ Age <65 years	R → Observation / p + Tam / CMFp + Tam
IV	Postmenopausal N+ Age 66–80 years	R → Observation / p + Tam

Update:

- See publications.

Related publications:

Aebi S, Gelber S, Castiglione-Gertsch M, *et al.* for the International Breast Cancer Study Group (IBCSG). Is chemotherapy alone adequate for young women with oestrogen-receptor-positive breast cancer? *Lancet* 2000; 355: 1869–1874 (Trials I–VI).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Anbazhagan R, Gelber RD, Bettelheim R, Goldhirsch A, Gusterson BA. Association of c-erbB-2 expression and S-phase fraction in the prognosis of node positive breast cancer. *Ann Oncol* 1991; 2: 47–53 (Trials I–IV).

Berclaz G, Li S, Price KN, *et al.* on behalf of the IBCSG. Body mass index as a prognostic feature in operable breast cancer: the International Breast Cancer Study Group experience. *Ann Oncol* 2004; 15: 875–884 (Trials I–VII).

Castiglione M, Gelber RD, Goldhirsch A. Adjuvant systemic therapy for breast cancer in the elderly: competing causes of mortality. *J Clin Oncol* 1990; 8: 519–526 (Trial IV).

Castiglione-Gertsch M, Johnsen C, Goldhirsch A, *et al.* for the International Breast Cancer Study Group. The International (Ludwig) Breast Cancer Study Group Trials I–IV: 15 years follow-up. *Ann Oncol* 1994; 5: 717–724 (Trials I–IV).

Castiglione-Gertsch M, Tattersall M, Hacking A, *et al.* for the IBCSG. Retreating recurrent breast cancer with the same CMF-containing regimen used as adjuvant therapy. *Eur J Cancer* 1997; 33: 2321–2325 (Trials I–V).

Cole BF, Gelber RD, Gelber S, Coates AS, Goldhirsch A. Polychemotherapy for early breast cancer: an overview of the randomised clinical trials with quality-adjusted survival analysis. *The Lancet* 2001; 358: 277–286 (Trial III).

Colleoni M, Bonetti M, Coates AS, *et al.* for the International Breast Cancer Study Group. Early start of adjuvant chemotherapy improves treatment outcome for premenopausal breast cancer patients with tumors not expressing estrogen receptor. *J Clin Oncol* 2000; 18: 584–590 (Trials I–V).

Colleoni M, Li S, Gelber RD, *et al.* for the International Breast Cancer Study Group. Relation between chemotherapy dose, oestrogen receptor expression, and body-mass index. *Lancet* 2005; 366: 1108–1110 (Trials I, II, V, VI).

Colleoni M, O'Neill A, Goldhirsch A, *et al.* for the International (Ludwig) Breast Cancer Study Group. Identifying breast cancer patients at high risk for bone metastases. *J Clin Oncol* 2000; 18: 3925–3935 (Trials I–VII).

Colleoni M, Price K, Castiglione-Gertsch M, Gelber R, Coates A, Goldhirsch A, for the International Breast Cancer Study Group (IBCSG). Mortality during adjuvant treatment of early breast cancer with cyclophosphamide, methotrexate, fluorouracil (CMF regimen). *Lancet* 1999; 354: 130–131 (Trials I–VII).

Colleoni M, Price K, Goldhirsch A, *et al.* for the IBCSG. Dose–response effect of adjuvant cyclophosphamide, methotrexate, fluorouracil (CMF) in node-positive breast cancer. *Eur J Cancer* 1998; 34: 1693–1700 (Trials I–V).

Colleoni M, Zahrieh D, Gelber RD, *et al.* Site of primary tumor has a prognostic role in operable breast cancer: the International Breast

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Cancer Study Group experience. *J Clin Oncol* 2005; 23: 1390–1400 (Trials I–VII, IX).

Crivellari D, Price K, Gelber RD, *et al.* for the IBCSG. Adjuvant endocrine therapy compared with no systemic therapy for elderly women with early breast cancer: 21-year results of International Breast Cancer Study Group Trial IV. *J Clin Oncol* 2003; 21: 4517–23.

Crivellari D, Price KN, Hagen M, *et al.* for the International (Ludwig) Breast Cancer Study Group (IBCSG): Routine tests during follow-up of patients after primary treatment for operable breast cancer. *Ann Oncol* 1995; 6: 769–776 (Trials I–V).

Davis BW, Gelber RD, Goldhirsch A, *et al.* Prognostic significance of peritumoral vessel invasion in clinical trials of adjuvant therapy for breast cancer with axillary lymph node metastasis. *Hum Pathol* 1985; 16: 1212–1218 (Trials I–IV).

Davis BW, Gelber RD, Goldhirsch A, *et al.* for the Ludwig Breast Cancer Study Group: Prognostic significance of tumor grade in clinical trials of adjuvant therapy for breast cancer with axillary lymph node metastasis. *Cancer* 1986; 58: 2662–2670 (Trials I–IV).

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Polychemotherapy for early breast cancer: an overview of the randomised trials. *Lancet* 1998; 352: 930–942 (Trial III).

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effect of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. *Lancet* 2005; 365: 1687–1717 (Trials II, III, VI, VII, IX, 11–93).

Gelber RD and Goldhirsch A, for the Ludwig Breast Cancer Study Group: A new endpoint for the assessment of adjuvant therapy in postmenopausal women with operable breast cancer. *J Clin Oncol* 1986; 4: 1772–1779 (Trial III).

Gianni L, Panzini I, Li S, *et al.* for the IBCSG. Ocular toxicity during adjuvant chemoendocrine therapy for early breast cancer: results from International Breast Cancer Study Group Trials. *Cancer* 2006; 106: 505–513 (Trials III, IV, VII, IX, 11–93, 12–93, 14–93).

Goldhirsch A, for the Ludwig Breast Cancer Study Group: Adjuvant treatment in operable breast cancer. *J Steroid Biochem* 1985; 23: 1155–1160 (Trials I–IV).

Goldhirsch A and Gelber RD, for the Ludwig Breast Cancer Study Group: Adjuvant treatment for early breast cancer: the Ludwig Breast Cancer Studies. *J Natl Cancer Inst Monogr* 1986; 1: 55–70 (Trials I–IV).

Goldhirsch A, Gelber RD, Castiglione M, for the Ludwig Breast Cancer Study Group: Relapse of breast cancer after adjuvant treatment in premenopausal and perimenopausal women: patterns and prognoses. *J Clin Oncol* 1988; 6: 89–97 (Trials I–II).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Goldhirsch A, Gelber RD, Castiglione M, *et al.* for the International Breast Cancer Study Group. The best available adjuvant treatments are within the framework of clinical trials. *Isr J Med Sci* 1995; 31: 145–154 (Trials I–V).

Goldhirsch A, Gelber R, Price K, *et al*. for the International Breast Cancer Study Group: Effect of systemic adjuvant treatment on first sites of breast cancer relapse. *Lancet* 1994; 343: 377–381 (Trials I–V).

Goldhirsch A, Gelber RD, Simes RJ, Glasziou P, Coates AS, for the Ludwig Breast Cancer Study Group. Costs and benefits of adjuvant therapy in breast cancer: A quality-adjusted survival analysis. *Classic Papers and Current Comments* 1996; 1: 152–160 (Trial III).

Goldhirsch A, Gelber RD, Yothers G, *et al.* Adjuvant therapy for very young women with breast cancer: need for tailored treatments. *J Natl Cancer Inst Monogr* 2001; 30: 44–51 (Trials I–VI).

Hedley DW, Rugg CA, Gelber RD, for the Ludwig Breast Cancer Study Group: Association of DNA index and S-phase fraction with prognosis of N+ early breast cancer. *Cancer Res* 1987; 47: 4729–4735 (Trials I–IV).

International Breast Cancer Study Group: Late effects of adjuvant oophorectomy and chemotherapy upon premenopausal breast cancer patients. *Ann Oncol* 1990; 1: 30–35 (Trial II).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials 1–14).

Ludwig Breast Cancer Study Group: Randomised trial of chemoendocrine therapy, endocrine therapy, and mastectomy alone in postmenopausal patients with operable breast cancer and axillary node metastasis. *Lancet* 1984; i: 1256–1260 (Trial III).

Ludwig Breast Cancer Study Group: A randomized trial of adjuvant combination chemotherapy with or without prednisone in premenopausal breast cancer patients with metastases in one to three axillary lymph nodes. *Cancer Res* 1985; 45: 4454–4459 (Trial I).

Ludwig Breast Cancer Study Group: Chemotherapy with or without oophorectomy in high-risk premenopausal patients with operable breast cancer. *J Clin Oncol* 1985; 3: 1059–1067 (Trial II).

Marini G, Murray S, Goldhirsch A, *et al.* The effect of adjuvant prednisone combined with CMF on patterns of relapse and occurrence of second malignancies in patients with breast cancer. *Ann Oncol* 1996; 7: 245–250 (Trial I).

Nathan B, Gusterson B, Jadayel D, *et al.* Expression of BCL-2 in primary breast cancer and its correlation with tumour phenotype. *Ann Oncol* 1994; 5: 409–414 (Trials I–IV).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Pedrazzini A, Gelber RD, Isley M, Castiglione M and Goldhirsch A, for the Ludwig Breast Cancer Study Group: First repeated bone scan in the observation of patients with operable breast cancer. *J Clin Oncol* 1986; 4: 389–394 (Trials I–IV).

Rudenstam C-M, for the Ludwig Breast Cancer Study Group: The Ludwig breast cancer studies in postmenopausal patients with axillary node metastasis. *Rev Endocrine-Related Cancer* 1985; 17: 25–32 (Trials III–IV).

Spataro V, Price K, Goldhirsch A, *et al.* for the International Breast Cancer Study Group (formerly Ludwig Group): Sequential estrogen receptor determinations from primary breast cancer and at relapse: prognostic and therapeutic relevance. *Ann Oncol* 1992; 3: 733–740 (Trials I–V).

Wallgren A, Bonetti M, Gelber RD, *et al.* for the IBCSG. Risk factors for locoregional recurrence among breast cancer patients: Results from International Breast Cancer Study Group Trials I Through VII. *J Clin Oncol* 2003; 21: 1205–1213 (Trials I–VII).

Topics:

- Axillary lymph node dissection
- Hormonal therapy, Node-positive breast cancer
- Ovarian suppression (Trial II)
- Pre- and perimenopausal patients (Trials I & II)
- Postmenopausal patients (Trials III & IV)
- Tamoxifen (Trials III & IV)

Keywords: Breast cancer, total mastectomy, prednisone, chemotherapy, endocrine therapy

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant perioperative chemotherapy. Ludwig/IBCSG Trial V

Coordinator(s): A. Goldhirsch
IOSI, Oncology Institute of Southern Switzerland
c/o Ospedale Italiano
Via Capelli
CH-6962 Viganello-Lugano
SWITZERLAND
and
Department of Medicine
European Institute of Oncology
I-20141 MILANO
ITALY
Tel: +41 91 811 79 23
Fax: +41 91 811 79 25
Email: aron.goldhirsch@ibcsg.org

Summary:

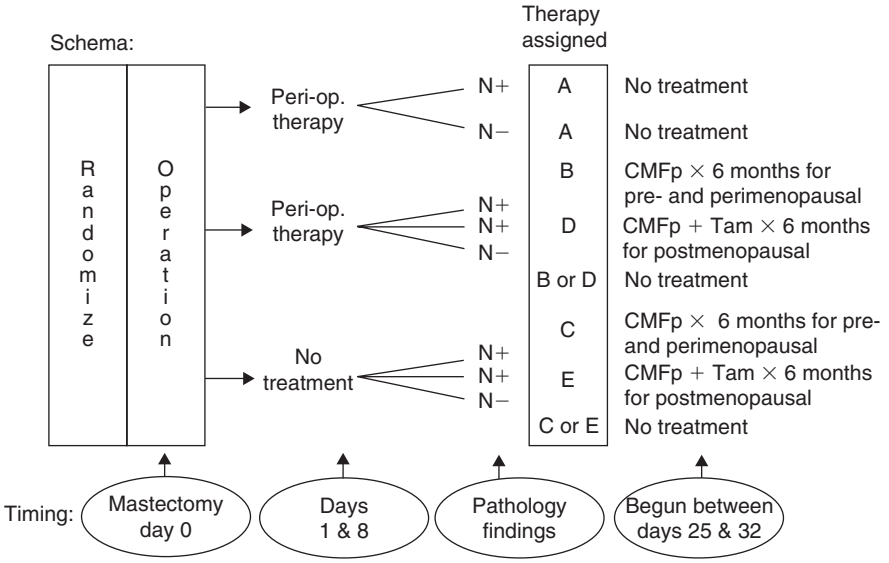
- Closed in December 1985 (opened in 1981)
- Final accrual: 2628 patients

Objectives:

- To assess the value of a combination of perioperative chemotherapy and conventionally timed adjuvant therapy as compared with perioperative therapy alone and conventionally timed therapy alone in N+ patients.
- To assess the value of perioperative chemotherapy in patients with proven breast cancer who are classified as N− post-surgically.
- To investigate the biological and toxic effects of perioperative therapy.
- To identify clinical, biological, and immuno-morphological risk factors in N− patients.
- To investigate the relationship of ER status to response to perioperative and/or conventionally timed adjuvant therapy in N+ and N− patients.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Scheme:



Update:

- See publications.

Related Publications:

Aebi S, Gelber S, Castiglione-Gertsch M, *et al.* for the International Breast Cancer Study Group (IBCSG). Is chemotherapy alone adequate for young women with oestrogen-receptor-positive breast cancer? *Lancet* 2000; 355: 1869–1874 (Trials I–VI).

Berclaz G, Li S, Price KN, *et al.* on behalf of the IBCSG. Body mass index as a prognostic feature in operable breast cancer: the International Breast Cancer Study Group experience. *Ann Oncol* 2004; 15: 875–884 (Trials I–VII).

Castiglione-Gertsch M, Tattersall M, Hacking A, *et al.* for the IBCSG. Retreating recurrent breast cancer with the same CMF-containing regimen used as adjuvant therapy. *Eur J Cancer* 1997; 33: 2321–2325 (Trials I–V).

Colleoni M, Bonetti M, Coates AS, *et al.* for the International Breast Cancer Study Group. Early start of adjuvant chemotherapy improves treatment outcome for premenopausal breast cancer patients with tumors not expressing estrogen receptor. *J Clin Oncol* 2000; 18: 584–590 (Trials I–V).

Colleoni M, Gelber S, Coates A, *et al.* for the IBCSG. Influence of endocrine-related factors on response to perioperative chemotherapy for

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

patients with node-negative breast cancer. *J Clin Oncol* 2001; 19: 4141–4149 (Trial V).

Colleoni M, Li S, Gelber RD, *et al.* for the International Breast Cancer Study Group. Relation between chemotherapy dose, oestrogen receptor expression, and body-mass index. *Lancet* 2005; 366: 1108–1110 (Trials I, II, V, VI).

Colleoni M, O'Neill A, Goldhirsch A, *et al.* for the International (Ludwig) Breast Cancer Study Group. Identifying breast cancer patients at high risk for bone metastases. *J Clin Oncol* 2000; 18: 3925–3935 (Trials I–VII).

Colleoni M, Price K, Castiglione-Gertsch M, Gelber R, Coates A, Goldhirsch A, for the International Breast Cancer Study Group (IBCSG). Mortality during adjuvant treatment of early breast cancer with cyclophosphamide, methotrexate, fluorouracil (CMF regimen). *Lancet* 1999; 354: 130–131 (Trials I–VII).

Colleoni M, Price K, Goldhirsch A, *et al.* for the IBCSG. Dose–response effect of adjuvant cyclophosphamide, methotrexate, fluorouracil (CMF) in node-positive breast cancer. *Eur J Cancer* 1998; 34: 1693–1700 (Trials I–V).

Colleoni M, Zahrieh D, Gelber RD, *et al.* Site of primary tumor has a prognostic role in operable breast cancer: the International Breast Cancer Study Group experience. *J Clin Oncol* 2005; 23: 1390–1400 (Trials I–VII, IX).

Cote RJ, Peterson HF, Chaiwun B, *et al.* The role of the immuno-histochemical detection of lymph node metastases in the management of breast cancer. *Lancet* 1999; 354: 896–900 (Trial V).

Crivellari D, Price KN, Hagen M, *et al.* for the International (Ludwig) Breast Cancer Study Group (IBCSG): Routine tests during follow-up of patients after primary treatment for operable breast cancer. *Ann Oncol* 1995; 6: 769–776 (Trials I–V).

Gelber S, Coates AS, Goldhirsch A, *et al.* for the International Breast Cancer Study Group (IBCSG). Effect of pregnancy on overall survival following the diagnosis of early stage breast cancer. *J Clin Oncol* 2001; 19: 1671–1675 (Trials V and VI).

Gelber RD, Goldhirsch A, Cavalli F. Quality-of-life adjusted evaluation of adjuvant therapies for operable breast cancer. *Ann Int Med* 1991; 114: 621–628 (Trial V).

Goldhirsch A, Castiglione M, Gelber RD for the International Breast Cancer Study Group: A single perioperative adjuvant chemotherapy course for node-negative breast cancer: five-year results of trial V. *J Natl Cancer Inst Monogr* 1992; 11: 89–96 (Trial V).

Goldhirsch A, Gelber R, Price K, *et al.* for the International Breast Cancer Study Group: Effect of systemic adjuvant treatment on first sites of breast cancer relapse. *Lancet* 1994; 343: 377–381 (Trials I–V).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Goldhirsch A, Gelber RD, Castiglione M, *et al.* for the International Breast Cancer Study Group. The best available adjuvant treatments are within the framework of clinical trials. *Isr J Med Sci* 1995; 31: 145–154 (Trials I–V).

Goldhirsch A, Gelber RD, Yothers G, *et al.* Adjuvant therapy for very young women with breast cancer: need for tailored treatments. *J Natl Cancer Inst Monogr* 2001; 30: 44–51 (Trials I–VI).

Gusterson BA, Gelber RD, Goldhirsch A, *et al.* for the International Breast Cancer Study Group: Prognostic importance of c-erbB-2 expression in breast cancer. *J Clin Oncol* 1992; 10: 1049–1056 (Trial V).

Gusterson BA, Gelber RD, Goldhirsch A, *et al.* for the International Breast Cancer Study Group: Prognostic importance of c-erbB-2 expression in breast cancer. *Classic Papers Curr Comm* 1996; 1: 32–40 (Trial V).

Gusterson BA, Gelber RD, Goldhirsch A, *et al.* for the International Breast Cancer Study Group: Prognostic importance of c-erbB-2 expression in breast cancer. *J Clin Oncol/Classic Papers and Current Comments* 2001; 5: 908–916 (Trial V).

Gusterson BA, Taylor CW, Price KN, Gelber RD, Säve-Söderberght J, Anbazhagan R, *et al.* Prognostic value of Helix Pomatia in breast cancer. *Br J Cancer* 1993; 68: 146–150 (Trial V).

International (Ludwig) Breast Cancer Study Group. Prognostic importance of occult axillary lymph node metastases from breast cancers. *Lancet* 1990; 335: 1565–1568 (Trial V).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials I–14).

Ludwig Breast Cancer Study Group. Combination adjuvant chemotherapy for node-positive breast cancer. Inadequacy of a single perioperative cycle. *New Engl J Med* 1988; 319: 677–683 (Trial V).

Ludwig Breast Cancer Study Group. On the safety of perioperative adjuvant chemotherapy with cyclophosphamide, methotrexate and 5-fluorouracil in breast cancer. *Eur J Cancer Clin Oncol* 1988; 24: 1305–1308 (Trial V).

Ludwig Breast Cancer Study Group. Prolonged disease-free survival after one course of perioperative adjuvant chemotherapy for node-negative breast cancer. *New Engl J Med* 1989; 320: 491–496 (Trial V).

Neville AM, Bettelheim R, Gelber R, *et al.* for the International Breast Cancer Study Group: Factors predicting treatment responsiveness and prognosis in node-negative breast cancer. *J Clin Oncol* 1992; 10: 696–705 (Trial V).

Pestalozzi BC, Peterson HF, Gelber RD, *et al.* The prognostic importance of thymidylate synthase expression in early breast cancer. *J Clin Oncol* 1997; 15: 1923–1931 (Trial V).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Pinder SE, Murray S, Ellis IO, *et al.* The importance of histological grade in invasive breast carcinoma and response to chemotherapy. *Cancer* 1998; 83: 1529–1539 (Trial V).

Spataro VJ, Litman H, Viale G, *et al.* Decreased immunoreactivity for p27 protein in patients with early-stage breast carcinoma is correlated with HER-2/neu overexpression and with benefit from one course of perioperative chemotherapy in patients with negative lymph node status: results from International Breast Cancer Study Group Trial V. *Cancer* 2003; 97: 1591–1600 (Trial V).

Spataro V, Price K, Goldhirsch A, *et al.* for the International Breast Cancer Study Group (formerly Ludwig Group): Sequential estrogen receptor determinations from primary breast cancer and at relapse: prognostic and therapeutic relevance. *Ann Oncol* 1992; 3: 733–740 (Trials I–V).

Trihia H, Murray S, Price K, *et al.* Ki-67 expression in breast carcinoma: its association with grading systems, clinical parameters, and other prognostic factors – A surrogate marker? *Cancer* 2003; 97: 1321–1331 (Trial V).

Wallgren A, Bonetti M, Gelber RD, *et al.* for the IBCSG. Risk factors for locoregional recurrence among breast cancer patients: results from International Breast Cancer Study Group Trials I through VII. *J Clin Oncol* 2003; 21: 1205–1213 (Trials I–VII).

Topics:

- Node-negative breast cancer
- Node-positive breast cancer
- Perioperative chemotherapy
- Tamoxifen

Keywords: Histologically or cytologically confirmed operable breast cancer, total mastectomy, CMF, tamoxifen, perioperative chemotherapy

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy in node-positive pre/perimenopausal breast cancer patients: CMF 3 *versus* 6 with or without reintroduction of chemotherapy.
IBCSG Trial VI

Coordinator(s): M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

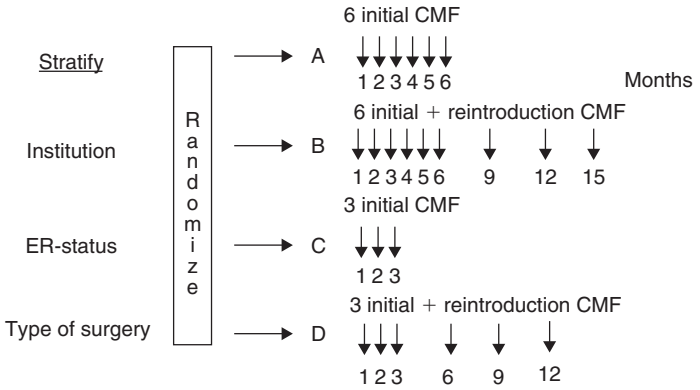
Summary:

- Closed in April 1993 (opened in July, 1986)
- Final accrual: 1505 patients

Objectives:

- To determine whether delayed administration of adjuvant chemotherapy (reintroduction) given after a treatment-free interval improves the outcome.
- To determine whether 3 cycles of adjuvant chemotherapy (given initially) are as effective as 6 cycles.

Scheme:



2 × 2 factorial design comparisons:

6 initial CMF (A + B) *versus* 3 initial CMF (C + D)
Reintroduction CMF (B + D) *versus* No reintroduction CMF (A + C)

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Update:

- See publications.

Related Publications:

Aebi S, Gelber S, Castiglione-Gertsch M, *et al.* for the International Breast Cancer Study Group (IBCSG). Is chemotherapy alone adequate for young women with oestrogen-receptor-positive breast cancer? *Lancet* 2000; 355: 1869–1874 (Trials I–VI).

Berclaz G, Li S, Price KN, *et al.* on behalf of the IBCSG. Body mass index as a prognostic feature in operable breast cancer: the International Breast Cancer Study Group experience. *Ann Oncol* 2004; 15: 875–884 (Trials I–VII).

Bernhard J, Hürny C, Coates A, Gelber R. Applying Quality of Life Principles in International Cancer Clinical Trials. *Int Clin Trials* 1996; 72: 693–705 (Trials VI–VII).

Bernhard J, Hürny C, Coates AS, *et al.* for the International Breast Cancer Study Group (IBCSG). Quality of life assessment in patients receiving adjuvant therapy for breast cancer: The IBCSG approach. *Ann Oncol* 1997; 8: 825–835 (Trials VI–VII).

Bernhard J, Hürny Ch, Coates AS, *et al.* for the IBCSG. Factors affecting baseline quality of life in two international adjuvant breast cancer trials. *Br J Cancer* 1998; 78: 686–693 (Trials VI–VII).

Bernhard J, Peterson HF, Coates AS, *et al.* for the International Breast Cancer Study Group. Quality of life assessment in international breast cancer study group (IBCSG) trials: practical issues and factors associated with missing data. *Stat Med* 1998; 17: 587–601 (Trials VI–VII).

Bernhard J, Sullivan M, Hürny C, Coates AS, Rudenstam C-M. Clinical relevance of single item quality of life indicators in cancer clinical trials. *Br J Cancer* 2001; 84: 1156–1165 (Trials VI–VII).

Coates AS, Hürny C, Peterson HF, *et al.* for the IBCSG. Quality of life scores predict outcome in metastatic but not in early breast cancer. *J Clin Oncol* 2000; 18: 3768–3774 (Trials VI–VII).

Colleoni M, Litman HJ, Castiglione-Gertsch M, *et al.* for the International Breast Cancer Study Group and the German Breast Cancer Study Group. Duration of adjuvant chemotherapy for breast cancer: A joint analysis of two randomised trials investigating 3 *versus* 6 courses of CMF (cyclophosphamide, methotrexate, and 5-fluorouracil). *Br J Cancer* 2002; 86: 1705–1714 (Trial VI).

Colleoni M, Li S, Gelber RD, *et al.* for the International Breast Cancer Study Group. Relation between chemotherapy dose, oestrogen receptor expression, and body-mass index. *Lancet* 2005; 366: 1108–1110 (Trials I, II, V, VI).

Colleoni M, O'Neill A, Goldhirsch A, *et al.* for the International (Ludwig) Breast Cancer Study Group. Identifying breast cancer patients at high risk for bone metastases. *J Clin Oncol* 2000; 18: 3925–3935 (Trials I–VII).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Colleoni M, Price K, Castiglione-Gertsch M, Gelber R, Coates A, Goldhirsch A, for the International Breast Cancer Study Group (IBCSG). Mortality during adjuvant treatment of early breast cancer with cyclophosphamide, methotrexate, fluorouracil (CMF regimen). *Lancet* 1999; 354: 130–131 (Trials I–VII).

Colleoni M, Zahrieh D, Gelber RD, *et al.* Site of primary tumor has a prognostic role in operable breast cancer: the International Breast Cancer Study Group experience. *J Clin Oncol* 2005; 23: 1390–1400 (Trials I–VII, IX).

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effect of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. *Lancet* 2005; 365: 1687–1717 (Trials II, III, VI, VII, IX, 11–93).

Gelber S, Coates AS, Goldhirsch A, *et al.* for the International Breast Cancer Study Group (IBCSG). Effect of pregnancy on overall survival following the diagnosis of early stage breast cancer. *J Clin Oncol* 2001; 19: 1671–1675 (Trials V and VI).

Goldhirsch A, Gelber R, Castiglione M, *et al.* and other members of the IBCSG. Menstrual cycle and timing of breast surgery in premenopausal node-positive breast cancer: Results of the International Breast Cancer Study Group (IBCSG) Trial VI. *Ann Oncol* 1997; 8: 751–756 (Trial VI).

Goldhirsch A, Gelber RD, Yothers G, *et al.* Adjuvant therapy for very young women with breast cancer: need for tailored treatments. *J Natl Cancer Inst Monogr* 2001; 30: 44–51 (Trials I–VI).

Gruber G, Bonetti M, Nasi ML, *et al.* for the IBCSG. Prognostic value of extracapsular tumor spread for locoregional control in premenopausal patients with node-positive breast cancer treated with classical cyclophosphamide, methotrexate, and fluorouracil: Long-term observations from International Breast Cancer Study Group Trial VI. *J Clin Oncol* 2005; 23: 7089–7097 (Trial VI).

Hürny C, Bernhard J, Coates A, *et al.* for the International Breast Cancer Study Group: Timing of baseline quality of life assessment in an international adjuvant breast cancer trial: its effect on patient estimation. *Ann Oncol* 1994; 5: 65–74 (Trials VI–VII).

Hürny C, Bernhard J, Coates A, *et al.* for the International Breast Cancer Study Group (IBCSG). Responsiveness of a single-item indicator *versus* a multi-item scale: assessment of emotional well-being in an international adjuvant breast cancer trial. *Med Care* 1996; 34: 234–248 (Trials VI–VII).

Hürny C, Bernhard J, Coates AS, *et al.* for the International Breast Cancer Study Group (IBCSG): Impact of adjuvant therapy on quality of life in women with node-positive operable breast cancer. *Lancet* 1996; 347: 1279–1284 (Trials VI–VII).

Hürny Ch, Bernhard J, Gelber RD, *et al.* for the International Breast Cancer Study Group: Quality of life measures for patients receiving

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

adjuvant therapy for breast cancer: an international trial. *Eur J Cancer* 1992; 28: 118–124 (Trials VI–VII).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials I–14).

Pagani O, O'Neill A, Castiglione M, *et al.* Prognostic impact of amenorrhoea after adjuvant chemotherapy in premenopausal breast cancer patients with axillary node involvement: results of the International Breast Cancer Study Group (IBCSG) Trial VI. *Eur J Cancer* 1998; 34: 632–640 (Trial VI).

The International Breast Cancer Study Group. Duration and reintroduction of adjuvant chemotherapy for node-positive premenopausal breast cancer patients. *J Clin Oncol* 1996; 14: 1885–1894 (Trial VI).

Wallgren A, Bernier J, Gelber RD, *et al.* for the International Breast Cancer Study Group: Timing of radiotherapy and chemotherapy following breast-conserving surgery for patients with node-positive breast cancer. *Int J Rad Onc Biol Phys* 1996; 35: 649–659 (Trials VI–VII).

Wallgren A, Bonetti M, Gelber RD, *et al.* for the IBCSG. Risk factors for locoregional recurrence among breast cancer patients: results from International Breast Cancer Study Group Trials I through VII. *J Clin Oncol* 2003; 21: 1205–1213 (Trials I–VII).

Topics:

- Node-positive breast cancer
- Premenopausal patients

Keywords: Breast cancer, chemotherapy, CMF, pre/perimenopausal patients, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant chemotherapy in node-positive postmenopausal breast cancer patients: endocrine *versus* chemo-endocrine *versus* chemo-endocrine with delayed chemotherapy.
IBCSG Trial VII

Coordinator(s): M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

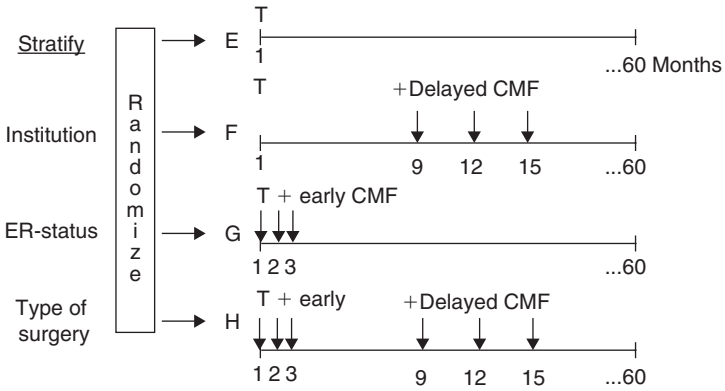
Summary:

- Closed in April 1993 (opened in July 1986)
- Final accrual: 1266 patients

Objectives:

- To determine whether chemo-endocrine therapy improves outcome compared to tamoxifen alone.
- To determine whether delayed single courses of adjuvant chemotherapy added to tamoxifen alone improve outcome.

Scheme:



2 × 2 factorial design comparisons:

Early CMF (G + H)	*versus*	No early CMF (E + F)
Delayed CMF (F + H)	*versus*	No delayed CMF (E + G)

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Update:

- See publications.

Related Publications:

Berclaz G, Li S, Price KN, *et al.* on behalf of the IBCSG. Body mass index as a prognostic feature in operable breast cancer: the International Breast Cancer Study Group experience. *Ann Oncol* 2004; 15: 875–884 (Trials I–VII).

Bernhard J, Hürny C, Coates A, Gelber R. Applying quality of life principles in international cancer clinical trials. *Int Clin Trials* 1996; 72: 693–705 (Trials VI–VII).

Bernhard J, Hürny C, Coates AS, *et al.* for the International Breast Cancer Study Group (IBCSG). Quality of life assessment in patients receiving adjuvant therapy for breast cancer: The IBCSG approach. *Ann Oncol* 1997; 8: 825–835 (Trials VI–VII).

Bernhard J, Hürny Ch, Coates AS, *et al.* for the IBCSG. Factors affecting baseline quality of life in two international adjuvant breast cancer trials. *Br J Cancer* 1998; 78: 686–693 (Trials VI–VII).

Bernhard J, Peterson HF, Coates AS, *et al.* for the International Breast Cancer Study Group. Quality of life assessment in international breast cancer study group (IBCSG) trials: practical issues and factors associated with missing data. *Stat Med* 1998; 17: 587–601 (Trials VI–VII).

Bernhard J, Sullivan M, Hürny C, Coates AS, Rudenstam C-M. Clinical relevance of single item quality of life indicators in cancer clinical trials. *Br J Cancer* 2001; 84: 1156–1165 (Trials VI–VII).

Bonetti M, Cole BF, Gelber RD. A method-of-moments estimation procedure for categorical quality-of-life data with nonignorable missingness. *JASA*1999; 94: 1025–1034 (Trial VII).

Bonetti M, Gelber RD. A graphical method to assess treatment-covariate interactions using the Cox model on subsets of the data. *Stat in Med* 2000; 19: 2595–2609 (Trial VII).

Colleoni M, Price K, Castiglione-Gertsch M, Gelber R, Coates A, Goldhirsch A, for the International Breast Cancer Study Group (IBCSG). Mortality during adjuvant treatment of early breast cancer with cyclophosphamide, methotrexate, fluorouracil (CMF regimen). *Lancet* 1999; 354: 130–131 (Trials I–VII).

Colleoni M, Li S, Gelber RD, *et al.* for the International Breast Cancer Study Group. Timing of CMF chemotherapy in combination with tamoxifen in postmenopausal women with breast cancer: role of endocrine responsiveness of the tumor. *Ann Oncol* 2005; 16: 716–725 (Trials VII and IX).

Colleoni M, O'Neill A, Goldhirsch A, *et al.* for the International (Ludwig) Breast Cancer Study Group. Identifying breast cancer patients at high risk for bone metastases. *J Clin Oncol* 2000; 18: 3925–3935 (Trials I–VII).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Colleoni M, Zahrieh D, Gelber RD, *et al.* Site of primary tumor has a prognostic role in operable breast cancer: the International Breast Cancer Study Group experience. *J Clin Oncol* 2005; 23: 1390–1400 (Trials I–VII, IX).

Crivellari D, Bonetti M, Castiglione-Gertsch M, *et al.* for the IBCSG. Burdens and benefits of adjuvant CMF and tamoxifen for elderly patients with breast cancer: the IBCSG Trial VII. *J Clin Oncol* 2000; 18: 1412–1422 (Trial VII).

Coates AS, Hürny C, Peterson HF, *et al.* for the IBCSG. Quality of life scores predict outcome in metastatic but not in early breast cancer. *J Clin Oncol* 2000; 18: 3768–3774 (Trials VI–VII).

Cole BF, Bonetti M, Zaslavsky AM, Gelber RD. A multistate Markov chain model for longitudinal, categorical quality-of-life data subject to non-ignorable missingness. *Stat Med* 2005; 24: 2317–2334 (Trial VII).

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effect of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. *Lancet* 2005; 365: 1687–1717 (Trials II, III, VI, VII, IX, 11–93).

Gelber RD, Bonetti M, Castiglione-Gertsch M, Coates AS, Goldhirsch A for the IBCSG. Tailoring adjuvant treatments for the individual breast cancer patient. *The Breast* 2003; 12: 558–568 (Trials VII and IX).

Gianni L, Panzini I, Li S, *et al.* for the IBCSG. Ocular toxicity during adjuvant chemoendocrine therapy for early breast cancer: results from International Breast Cancer Study Group Trials. *Cancer* 2006; 106:505–513 (Trials III, IV, VII, IX, 11–93, 12–93, 14–93).

Hürny Ch, Bernhard J, Gelber RD, *et al.* for the International Breast Cancer Study Group: Quality of life measures for patients receiving adjuvant therapy for breast cancer: an international trial. *Eur J Cancer* 1992; 28: 118–124 (Trials VI–VII).

Hürny C, Bernhard J, Coates A, *et al.* for the International Breast Cancer Study Group: Timing of baseline quality of life assessment in an international adjuvant breast cancer trial: its effect on patient estimation. *Ann Oncol* 1994; 5: 65–74 (Trials VI–VII).

Hürny C, Bernhard J, Coates A, *et al.* for the International Breast Cancer Study Group (IBCSG). Responsiveness of a single-item indicator *versus* a multi-item scale: assessment of emotional well-being in an international adjuvant breast cancer trial. *Med Care* 1996; 34: 234–248 (Trials VI–VII).

Hürny C, Bernhard J, Coates AS, *et al.* for the International Breast Cancer Study Group (IBCSG): Impact of adjuvant therapy on quality of life in women with node-positive operable breast cancer. *Lancet* 1996; 347: 1279–1284 (Trials VI–VII).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials I–14).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Regan MM, Gelber RD. Predicting response to systemic treatments: learning from the past to plan for the future. *The Breast* 2005; 14: 582–593 (Trials VII and IX).

The International Breast Cancer Study Group. Effectiveness of adjuvant chemotherapy in combination with tamoxifen for node-positive postmenopausal breast cancer patients. *J Clin Oncol* 1997; 15: 1385–1393 (Trial VII).

Wallgren A, Bernier J, Gelber RD, *et al.* for the International Breast Cancer Study Group: Timing of radiotherapy and chemotherapy following breast-conserving surgery for patients with node-positive breast cancer. *Int J Rad Onc Biol Phys* 1996; 35: 649–659 (Trials VI–VII).

Wallgren A, Bonetti M, Gelber RD, *et al.* for the IBCSG. Risk factors for locoregional recurrence among breast cancer patients: results from International Breast Cancer Study Group Trials I through VII. *J Clin Oncol* 2003; 21: 1205–1213 (Trials I–VII).

Topics:

- Node-positive breast cancer
- Postmenopausal patients
- Tamoxifen

Keywords: Node-positive breast cancer, chemotherapy, CMF, tamoxifen, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy in pre- and perimenopausal patients with node-negative breast cancer. Observation *versus* LH–RH analogue *versus* CMF *versus* CMF + LN–RH analogue.
IBCSG Trial VIII

Coordinator(s):

M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

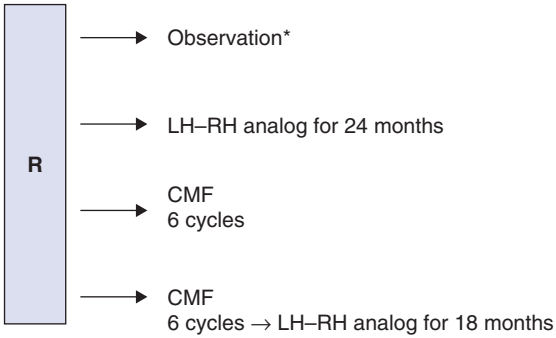
Summary:

- Closed in October 1999 (opened in March 1990)
- Final accrual: 1111 patients

Objectives:

- To determine whether the use of an LH–RH analogue following 6 months of cyclophosphamide, methotrexate, fluorouracil (CMF) chemotherapy reduces relapse and prolongs survival as compared to the use of either a 2-year administration of an LH–RH analogue alone or the use of 6 months of CMF alone.
- To investigate the patients' perceptions on well-being and coping during adjuvant treatment, after therapy but before relapse, and after relapse.

Scheme:



* Observation arm dropped in April 1992

Update:

- See publications.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Related Publications:

Aebi S and Castiglione-Gertsch M. Adjuvant endocrine therapy for the very young patients. *The Breast* 2003; 12: 509–515 (Trial VIII).

Castiglione-Gertsch M, Gelber RD, Coates AS, O'Neill A, Goldhirsch A, for the IBCSG. Systemic adjuvant treatment for premenopausal node-negative breast cancer. *Eur J Canc*2000; 36: 549–550 (Trial VIII).

International Breast Cancer Study Group. Adjuvant chemotherapy followed by goserelin *versus* either modality alone for premenopausal lymph node-negative breast cancer: a randomized trial. *J Natl Cancer Inst* 2003; 95: 1833–1846 (Trial VIII).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials 1–14).

Topics:

- Node-negative breast cancer
- Premenopausal patients

Keywords:

Pre- and perimenopausal patients, oral CMF, LH–RH analogue, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy in postmenopausal patients with node-negative breast cancer. Tamoxifen *versus* CMF followed by tamoxifen.
IBCSG Trial IX

Coordinator(s):

M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

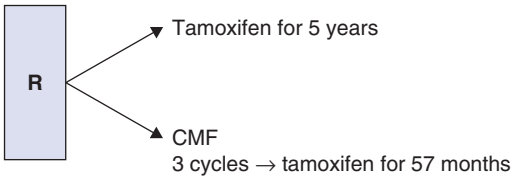
Summary:

- Closed in August 1999 (opened in October 1988)
- Final accrual: 1715 patients

Objectives:

- To evaluate if the addition of 3 cycles of initial chemotherapy to adjuvant tamoxifen improves outcome.
- To evaluate quality of life.

Scheme:



Update:

- See publications.

Related Publications:

Bernhard J, Zahrieh D, Coates AS, *et al.* for the IBCSG. Quantifying trade-offs: quality of life and quality-adjusted survival in a randomised trial of chemotherapy in postmenopausal patients with lymph node-negative breast cancer. *Br J Cancer* 2004; 91: 1893–1901 (Trial IX).

Bonetti M, Gelber RD. Patterns of treatment effects in subsets of patients in clinical trials. *Biostatistics* 2004; 5 (3): 465–481 (Trial IX).

Castiglione-Gertsch M for the International Breast Cancer Study Group. Endocrine responsiveness and tailoring adjuvant therapy for postmenopausal lymph node-negative breast cancer: a randomized trial of the International Breast Cancer Study Group. *Am J Oncol Rev* 2002; 1: 286–289 (Trial IX).

Colleoni M, Li S, Gelber RD, *et al.* for the International Breast Cancer Study Group. Timing of CMF chemotherapy in combination with tamoxifen in postmenopausal women with breast cancer: role of

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

endocrine responsiveness of the tumor. *Ann Oncol* 2005; 16: 716–725 (Trials VII and IX).

Colleoni M, Zahrieh D, Gelber RD, *et al.* Site of primary tumor has a prognostic role in operable breast cancer: the International Breast Cancer Study Group experience. *J Clin Oncol* 2005; 23: 1390–1400 (Trials I–VII, IX).

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effect of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. *Lancet* 2005; 365: 1687–1717 (Trials II, III, VI, VII, IX, 11–93).

Gelber RD, Bonetti M, Castiglione-Gertsch M, Coates AS, Goldhirsch A for the IBSCG. Tailoring adjuvant treatments for the individual breast cancer patient. *The Breast* 2003; 12: 558–568 (Trials VII and IX).

Gianni L, Panzini I, Li S, *et al.* for the IBCSG. Ocular toxicity during adjuvant chemoendocrine therapy for early breast cancer: results from International Breast Cancer Study Group Trials. *Cancer* 2006; 106: 505–513 (Trials III, IV, VII, IX, 11–93, 12–93, 14–93).

International Breast Cancer Study Group. Endocrine responsiveness and tailoring adjuvant therapy for postmenopausal lymph node negative breast cancer: a randomized trial. *J Natl Cancer Inst* 2002; 94: 1054–1065 (Trial IX).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials 1–14).

Regan MM, Gelber RD. Predicting response to systemic treatments: learning from the past to plan for the future. *The Breast* 2005; 14: 582–593 (Trials VII and IX).

Topics:

- Hormonal therapy
- Node-negative breast cancer
- Postmenopausal patients
- Tamoxifen

Keywords: Combination CMF-tamoxifen, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Surgical therapy with or without axillary node clearance for breast cancer in elderly patients who receive adjuvant therapy with tamoxifen. IBCSG Trial 10–93

Coordinator(s): D. Crivellari
Centro di Riferimento Oncologico Aviano
Via Pedemontana Occ. 12
I-33081 AVIANO
ITALY
Tel: +39 0434 659 190
Fax: +39 0434 652 182
Email: dcrivellari@cro.it

C.M. Rudenstam
Bohusgatan 26
S-41139 GÖTEBORG
SWEDEN
Tel: +46 31 164 511
Fax: +46 31 602 172
Email: c-m.rudenstam@telia.com

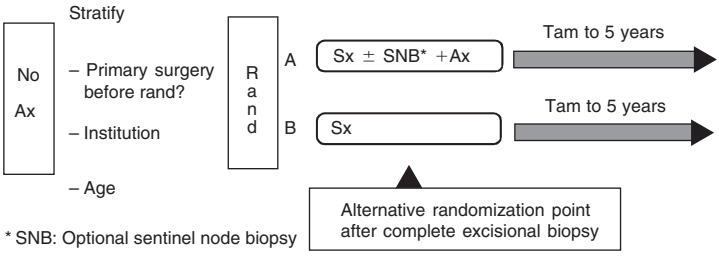
Summary:

- Closed in December 2002 (opened in May 1993)
- Final accrual: 473 patients

Objective:

- To compare the impact of avoiding axillary dissection in terms of the quality of life for older (⩾60) patients who receive surgery and adjuvant tamoxifen.

Scheme:



Update:

- See publications.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Related publications:

International Breast Cancer Study Group. Randomized trial comparing axillary clearance *versus* no axillary clearance in older patients with breast cancer: first results of International Breast Cancer Study Group Trial 10–93. *J Clin Oncol* 2006; 24: 337–344.

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials I–14).

Topics:

- Axillary lymph node dissection
- Elderly patients
- Postmenopausal patients
- Tamoxifen

Keywords: Elderly patients, breast cancer, axillary clearance, tamoxifen, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy for premenopausal patients with node-positive breast cancer who are suitable for endocrine therapy alone.
IBCSG Trial 11–93

Coordinator(s): B. Thürlimann
Senologie-Zentrum Ostschweiz
Kantonsspital
CH-9007 ST GALLEN
SWITZERLAND
Tel: +41 71 494 1111
Fax: +41 71 494 6368
Email: beat.thuerlimann@kssg.ch

M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

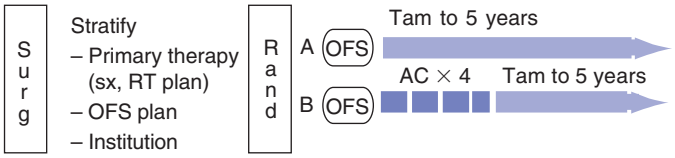
Summary:

- Closed in November 1998 (opened in May 1993)
- Final accrual: 174 patients

Objectives:

- To evaluate if the addition of chemotherapy (AC × 4) to endocrine therapy alone (ovarian function suppression (OFS), tamoxifen) improves outcome.
- To assess quality of life.

Scheme:



Update:

- See publications.

Related Publications: Gianni L, Panzini I, Li S, *et al.* for the IBCSG. Ocular toxicity during adjuvant chemoendocrine therapy for early breast cancer: results from International Breast Cancer Study Group Trials. *Cancer* 2006; 106: 505–513 (Trials III, IV, VII, IX, 11–93, 12–93, 14–93).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

International Breast Cancer Study Group. Randomized controlled trial of ovarian function suppression plus tamoxifen *versus* the same endocrine therapy plus chemotherapy: Is chemotherapy necessary for premenopausal women with node-positive, endocrine responsive breast cancer? First results of International Breast Cancer Study Group Trial 11–93. *The Breast* 2001; 10 (Suppl 3): 130–138 (Trial 11–93).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials I–14).

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). Effect of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. *Lancet* 2005; 365: 1687–1717 (Trials II, III, VI, VII, IX, 11–93).

Topics:

- Hormonal therapy
- Hormone-receptor-positive breast cancer
- Node-positive breast cancer
- Ovarian ablation
- Premenopausal patients
- Tamoxifen

Keywords: Breast cancer, endocrine therapy, ovarian ablation, AC, tamoxifen, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy for post/perimenopausal patients with node-positive breast cancer who have estrogen-receptor-positive tumors. IBCSG Trial 12–93

Coordinator(s):

E. Simoncini
Oncologia Medica
Spedali Civili
Piazzale Spedali Civili 1
I-25123 BRESCIA
ITALY
Tel: +39 03 0399 5410
Fax: +39 03 0370 0017
Email: bscivile@ns.numerica.it

O. Pagani
IOSI, Oncology Institute of Southern Switzerland
c/o Ospedale Beata Vergine
CH-6850 MENDRISIO
SWITZERLAND
Tel: +41 91 811 3111
Fax: +41 91 811 3038
Email: olivia.pagani@ibcsg.org

A. Goldhirsch
IOSI, Oncology Institute of Southern Switzerland
c/o Ospedale Italiano
Via Capelli
CH-6962 Viganello-Lugano
SWITZERLAND
and
Department of Medicine
European Institute of Oncology
I-20141 MILANO
ITALY
Tel: +41 91 811 79 23
Fax: +41 91 811 79 25
Email: aron.goldhirsch@ibcsg.org

Summary:

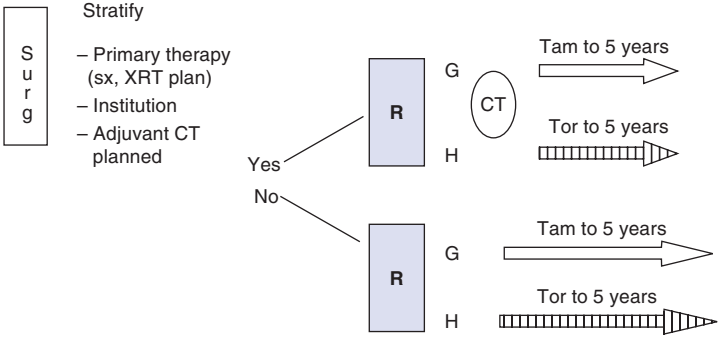
- Closed in August 1999 (opened in May 1993)
- Final accrual: 452 patients

Objectives:

- To evaluate if toremifene is equally effective as tamoxifen in controlling breast cancer.
- To assess quality of life.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Scheme:



Update:

- See publications.

Related Publications:

Gianni L, Panzini I, Li S, *et al.* for the IBCSG. Ocular toxicity during adjuvant chemoendocrine therapy for early breast cancer: results from International Breast Cancer Study Group Trials. *Cancer* 2006; 106: 505–513. (Trials III, IV, VII, IX, 11–93, 12–93, 14–93).

International Breast Cancer Study Group. Toremifene and tamoxifen are equally effective for early-stage breast cancer: first results of International Breast Cancer Study Group Trials 12–93 and 14–93. *Ann Oncol* 2004; 15: 1749–1759 (Trials 12–93 and 14–93).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials 1–14).

Topics:

- Postmenopausal patients
- Hormonal therapy
- Hormone-receptor-positive breast cancer
- Tamoxifen

Keywords:

ER-positive breast cancer, post/perimenopausal patients, toremifene, tamoxifen, chemotherapy, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy for premenopausal patients with node-positive breast cancer who are not suitable for endocrine therapy alone.
IBCSG Trial 13–93

Coordinator(s): M. Colleoni
European Institute of Oncology, EIO
Unit of Research in Medical Senology
Department of Medicine
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 57489 439
Fax: +39 02 57489 581
Email: marco.colleoni@ieo.it

M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

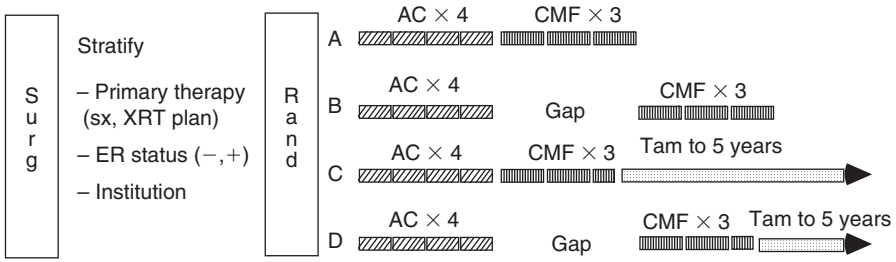
Summary:

- Closed in August 1999 (opened in May 1993)
- Final accrual: 1294 patients

Objectives:

- To evaluate if a 16-week treatment-free interval between two sequential chemotherapy regimens (AC × 4, CMF × 3) improves outcome.
- To evaluate if tamoxifen maintenance following chemotherapy improves outcome.
- To assess quality of life.

Scheme:



Gap = 16-week treatment-free interval

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Update:
- See publications.

Related Publications:

International Breast Cancer Study Group. Tamoxifen after adjuvant chemotherapy for premenopausal women with lymph node-positive breast cancer: IBCSG Trial 13–93. *J Clin Oncol* 2006; 24: 1332–1341.

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials I–14).

Topics:
- Anthracyclines
- Premenopausal patients
- Node-positive breast cancer
- Hormonal therapy
- Tamoxifen

Keywords: Node-positive breast cancer, premenopausal patients, AC, CMF, tamoxifen, treatment-free interval, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy for post perimenopausal patients with node-positive breast cancer who are not suitable for endocrine therapy alone. IBCSG Trial 14–93

Coordinator(s):

O. Pagani
IOSI, Oncology Institute of Southern Switzerland
Ospedale Beata Vergine
CH-6850 MENDRISIO
SWITZERLAND
Tel: +41 91 811 3111
Fax: +41 92 811 3038
Email: olivia.pagani@ibcsg.org

E. Simoncini
Oncologia Medica
Spedali Civili
Piazzale Spedali Civili 1
I-25123 BRESCIA
ITALY
Tel: +39 03 0399 5410
Fax: +39 03 0370 0017
Email: bscivile@ns.numerica.it

A. Goldhirsch
IOSI, Oncology Institute of Southern Switzerland
c/o Ospedale Italiano
Via Capelli
CH-6962 VIGANELLO-LUGANO
SWITZERLAND
and
Department of Medicine
European Institute of Oncology
I-20141 MILANO
ITALY
Tel: +41 91 811 79 23
Fax: +41 91 811 79 25
Email: aron.goldhirsch@ibcsg.org

Summary:

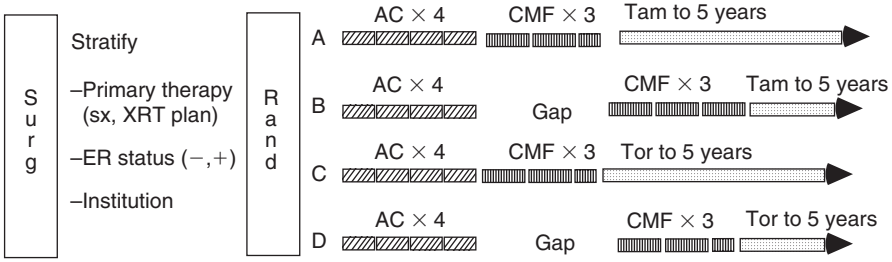
- Closed in August 1999 (opened in May 1993)
- Final accrual: 969 patients

Objectives:

- To evaluate if a 16-week treatment-free interval between two sequential chemotherapy regimens (AC × 4, CMF × 3) improves outcome.
- To evaluate if toremifene is equally effective as tamoxifen in controlling breast cancer following completion of all chemotherapy.
- To assess quality of life.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Scheme:



*Gap = 16-week treatment-free interval

Update:

- See publications.

Related Publications:

Gianni L, Panzini I, Li S, *et al.* for the IBCSG. Ocular toxicity during adjuvant chemoendocrine therapy for early breast cancer: results from International Breast Cancer Study Group Trials. *Cancer* 2006; 106: 505–513 (Trials III, IV, VII, IX, 11–93, 12–93, 14–93).

International Breast Cancer Study Group. Toremifene and tamoxifen are equally effective for early-stage breast cancer: first results of International Breast Cancer Study Group Trials 12–93, 14–93. *Ann Oncol* 2004; 15: 1749–1759 (Trials 12–93, 14–93).

Kitchen PRB, Smith HJ, Henderson MA, *et al.* Tubular carcinoma of the breast: Prognosis and response to adjuvant systemic therapy. *ANZ J Surg* 2001; 71: 27–31 (Trials 1–14).

Topics:

- Anthracyclines
- Hormonal therapy
- Node-positive breast cancer
- Postmenopausal patients
- Tamoxifen

Keywords: Node-positive breast cancer, post/perimenopausal patients, AC, CMF, tamoxifen, toremifene, treatment-free interval, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: High dose EC × 3 supported by PBSC *versus* EC/AC × 4 followed by CMF as adjuvant treatment for high-risk operable Stage II and Stage III breast cancer in premenopausal and young postmenopausal (<65 years) patients. IBCSG Trial 15–95

Coordinator(s):
R. Basser
CSL Limited
45 Poplar Road
Parkville, VIC 3052
AUSTRALIA
Tel: +61 3 9389 1569
Fax: +61 3 9388 2351
Email: russell.basser@csl.com.au

M. Castiglione
IBCSG Coordinating Center
Effingerstr. 40
CH-3008 BERN
SWITZERLAND
Tel: +41 31 389 9391
Fax: +41 31 389 9235
Email: monica.castiglione@ibcsg.org

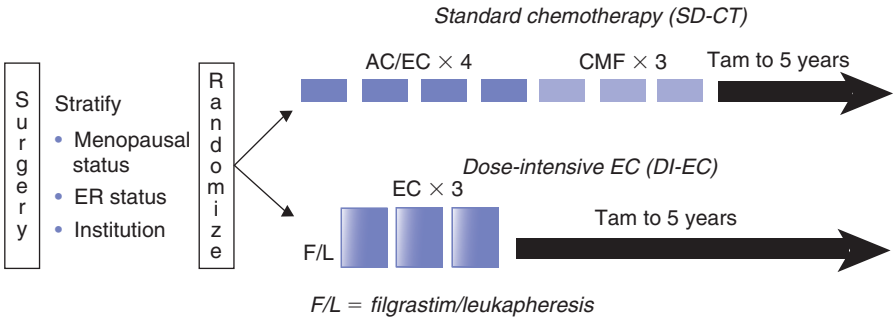
Summary:

- Closed in March 2000 (opened in July 1995)
- Final accrual: 344 patients

Objectives:

- To evaluate if a regimen of high-dose chemotherapy (EC × 3) improves outcome when compared with standard dose chemotherapy (AC × 4 → CMF × 3) for patients with a high-risk of recurrence.
- To evaluate quality of life.

Scheme:



F/L = filgrastim/leukapheresis

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Update:
- See publications.

Related Publications:
International Breast Cancer Study Group. Multicycle dose-intensive chemotherapy for women with high-risk primary breast cancer: results of International Breast Cancer Study Group Trial 15–95. *J Clin Oncol* 2006; 24: 370–378.

Topics:
- Anthracyclines
- High-dose chemotherapy
- Hormone-receptor-negative breast cancer
- Node-positive breast cancer
- Postmenopausal patients
- Premenopausal patients
- Tamoxifen

Keywords:
High-risk operable Stage II/III breast cancer, high-dose chemotherapy, peripheral blood progenitor cells, tamoxifen, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Adjuvant therapy for postmenopausal patients with operable breast cancer who have estrogen-receptor or progesterone-receptor-positive tumors. Tamoxifen *versus* letrozole *versus* tamoxifen followed by letrozole *versus* letrozole followed by tamoxifen.
BIG 1–98 / IBCSG Trial 18–98

Coordinator(s):

B. Thürlimann
Senologie-Zentrum Ostschweiz
Kantonsspital
CH-9007 St Gallen
SWITZERLAND
Tel: +41 71 494 1111
Fax: +41 71 494 6368
Email: beat.thuerlimann@kssg.ch

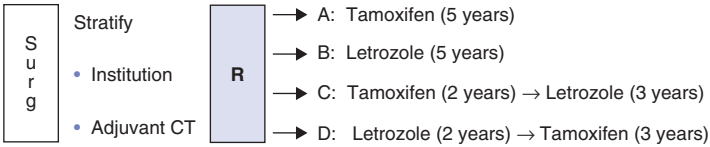
Summary:

- Closed in May 2003 (opened in March 1998)
- Final accrual: 8028 patients

Objectives:

- To compare letrozole × 5 years *versus* tamoxifen × 5 years.
- To compare a sequence of adjuvant endocrine therapies *versus* a continuous course of a single endocrine agent.

Scheme:



Update:

- *Amendment 5 released in April 2005:*
- Unblinding and information of patients on treatment arm A (Tamoxifen).

Substudies:

- New Bone substudy opened May 2004, target accrual: 660 patients.
- Cognitive Function substudy opened April 2005, target accrual: 296 patients
- Fingernail Pilot substudy opened April 2005, target accrual: 60 patients
- Bone Mineral Density substudy closed February 2003.
- General Safety/Lipid Profile substudy closed February 2003.

First results published, see publications.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Related Publications: BIG 1–98 Collaborative. A comparison of letrozole and tamoxifen in postmenopausal women with early breast cancer. *New Engl J Med* 2005; 353: 2747–2757 (Trial 18–98).

Topics:

- Aromatase inhibitors
- Hormone-receptor-positive breast cancer
- Postmenopausal patients
- Tamoxifen

Keywords: Hormone-receptor-positive breast cancer, letrozole, tamoxifen, mono/sequential therapy

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Maintenance chemotherapy in hormone non-responsive breast cancer: low-dose cytotoxics as "anti-angiogenesis treatment" following adjuvant induction chemotherapy for patients with ER-negative and PgR-negative breast cancer.
IBCSG Trial 22–00

Coordinator(s): M. Colleoni
European Institute of Oncology, EIO
Unit of Research in Medical Senology
Department of Medicine
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 574 89 439
Fax: +39 02 57489 581
Email: marco.colleoni@ieo.it

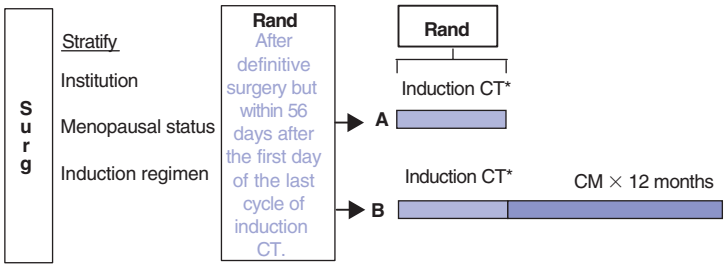
Summary:

- Date of activation: November 2000
- Target accrual: 900 patients

Objective:

- To evaluate the efficacy of a low-dose chemotherapy regimen, hypothesized to have anti-angiogenic activity, administered following a standard chemotherapy program in patients whose tumors are not endocrine therapy-responsive.

Scheme:



* Approved Induction CT Regimens.
Please refer to the protocol for details.

Update:

- Amendment 3: November 2005.
- Serum Substudy: opened June 2002, target accrual: 170 patients.

Related Publications: Price KN, Goldhirsch A for the IBCSG. Clinical trial update: International Breast Cancer Study Group. *Breast Cancer Res* 2005; 7: 252–254 (commentary).

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Topics:

- Hormone-receptor-negative breast cancer
- Low-dose chemotherapy
- Premenopausal patients or postmenopausal patients
- Elderly patients and young patients
- Treatment tailoring

Keywords: Hormone non-responsive breast cancer, anti-angiogenesis, maintenance chemotherapy, CM maintenance, tailored chemotherapy, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: A randomized trial of axillary dissection *versus* no axillary dissection for patients with clinically node-negative breast cancer and micrometastases in the sentinel node.
IBCSG Trial 23–01

Coordinator(s):
V. Galimberti
European Institute of Oncology EIO
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 57489 717
Fax: +39 02 57489 780
Email: viviana.galimberti@ieo.it

S. Zurrida
European Institute of Oncology EIO
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 57489 608 / 215
Email: stefano.zurrida@ieo.it

U. Veronesi
European Institute of Oncology EIO
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 57224 / 215
Fax: +39 02 57489 210
Email: umberto.veronesi@ieo.it

Summary:

- Date of activation: December 2001
- Target accrual: 1960 patients

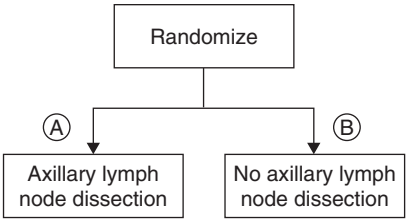
Objective:

- To compare axillary dissection *versus* no axillary dissection in terms of disease-free survival in patients with one micrometastasis in a sentinel node.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Scheme:

Patients with
- Clinically node-negative breast cancer
- Size of largest tumour lesion ≤ 5 cm
- Sentinel node biopsy
- SN micrometastases ≤ 2 mm



Update:
- Amendment 2: June 2006.

Related Publications: None available

Topics:
- Axillary lymph node dissection
- Postmenopausal patients
- Premenopausal patients
- Sentinel node micrometastasis
- Sentinel node resection

Keywords: Clinically node-negative breast cancer, sentinel node micrometastasis, axillary dissection, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Suppression of Ovarian Function Trial (SOFT).
A Phase III trial evaluating the role of ovarian function suppression (OFS) and the role of exemestane as adjuvant therapies for premenopausal women with endocrine-responsive breast cancer. Tamoxifen *versus* OFS + tamoxifen *versus* OFS + exemestane.
BIG 2–02/IBCSG Trial 24–02

Coordinator(s):

BIG:
P. Francis
Peter MacCallum Cancer Institute
St Andrews Place
3002 East Melbourne, VIC
AUSTRALIA
Tel: +61 3 965 61190
Fax: +61 3 965 61408
Email: pfrancis@petermac.unimelb.edu.au

US Intergroup:
G. Fleming
University of Chicago Medical Center
Section of Hematology/Oncology
5841 South Maryland Ave, MC 2115
CHICAGO, IL 60637-1470
USA
Tel: +1 773 702 6712
Fax: +1 773 702 0963
Email: gfleming@medicine.bsd.uchicago.edu

Summary:

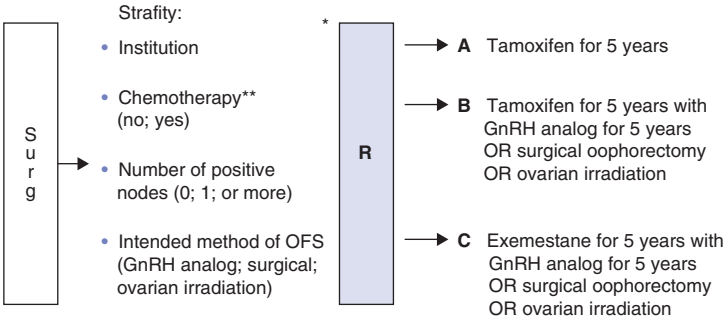
- Date of activation: August 2003
- Target accrual: 3000 patients

Objectives:

- To evaluate the role of ovarian function suppression and the role of exemestane as adjuvant therapies for premenopausal women with endocrine-responsive breast cancer.
- To assess quality of life.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Scheme:



*Patients may have received tamoxifen or aromatase inhibitor prior to randomization

**Any standard chemotherapy

Update:

- Amendment 1: October 2005.

Related Publications:

Dellapasqua S, Castiglione-Gertsch M. The choice of systemic adjuvant therapy in receptor-positive early breast cancer. *Eur J Cancer* 2005; 41: 357–364 (commentary).

Dellapasqua S, Colleoni M, Gelber RD, Goldhirsch A. Adjuvant endocrine therapy for premenopausal women with early breast cancer. *J Clin Oncol* 2005; 23: 1736–1750 (commentary).

Price KN, Goldhirsch A for the IBCSG. Clinical trial update: International Breast Cancer Study Group. *Breast Cancer Res* 2005; 7: 252–254 (commentary).

Topics:

- Aromatase inhibitors
- Hormone-receptor-positive breast cancer
- Ovarian function suppression
- Premenopausal patients
- Tamoxifen
- Treatment tailoring
- Young patients

Keywords: Endocrine-responsive breast cancer, premenopausal patients, ovarian function suppression, tamoxifen, exemestane, tailored treatment, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Tamoxifen and Exemestane Trial (TEXT)
A Phase III trial evaluating the role of exemestane plus GnRH analogue as adjuvant therapy for premenopausal women with endocrine-responsive breast cancer. Ovarian function suppression + tamoxifen *versus* ovarian function suppression + exemestane.
BIG 3–02/IBCSG Trial 25–02

Coordinator(s):

BIG:
O. Pagani
IOSI, Oncology Institute of Southern Switzerland
Ospedale Beata Vergine
6850 MENDRISIO
SWITZERLAND
Tel: +41 79 208 77 85
Fax: +41 91 811 30 27
Email: olivia.pagani@ibcsg.org

US Intergroup:
B. Walley
Tom Baker Cancer Centre
1331 – 29 St. N.W.
CALGARY, ALBERTA
CANADA
Tel: +1 403 521 3688
Fax: +1 403 283 1651
Email: bwalley@CancerBoard.ab.ca

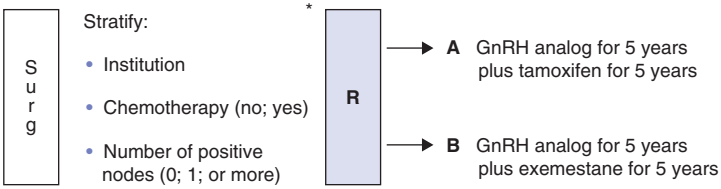
Summary:

- Date of activation: August 2003
- Target accrual: 1845 patients

Objectives:

- To compare GnRH analogue plus exemestane *versus* GnRH analogue plus tamoxifen for premenopausal women with endocrine-responsive breast cancer.
- To assess quality of life.

Scheme:



*Randomization prior to receiving any adjuvant systemic therapy

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Update:

- Amendment 1: October 2005.

Related Publications:

Dellapasqua S, Castiglione-Gertsch M. The choice of systemic adjuvant therapy in receptor-positive early breast cancer. *Eur J Cancer* 2005; 41: 357–364 (commentary).

Dellapasqua S, Colleoni M, Gelber RD, Goldhirsch A. Adjuvant endocrine therapy for premenopausal women with early breast cancer. *J Clin Oncol* 2005; 23: 1736–1750 (commentary).

Price KN, Goldhirsch A for the IBCSG. Clinical trial update: International Breast Cancer Study Group. *Breast Cancer Res* 2005; 7: 252–254 (commentary).

Topics:

- Aromatase inhibitors
- Hormone-receptor-positive breast cancer
- Ovarian function suppression
- Premenopausal patients
- Tamoxifen
- Treatment tailoring
- Young patients

Keywords: Endocrine-responsive breast cancer, premenopausal patients, ovarian function suppression, tamoxifen, exemestane, tailored treatment, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Premenopausal Endocrine Responsive Chemotherapy Trial (PERCHE)
A Phase III trial evaluating the role of chemotherapy as adjuvant therapy for premenopausal women with endocrine-responsive breast cancer who receive endocrine therapy.
Chemotherapy + OFS + tamoxifen/exemestane *versus* OFS + tamoxifen/exemestane.
BIG 4–02/IBCSG Trial 26–02

Coordinator(s):

BIG:
R. Torrisi
European Institute of Oncology, EIO
Unit of Research in Medical Senology
Department of Medicine
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 574 89 482
Fax +39 02 57489 581
Email: rosalba.torrisi@ieo.it

US Intergroup:
E.A. Perez
Mayo Clinic Jacksonville
4500 San Pablo Road S
JACKSONVILLE, FL 32224-1865
USA
Tel: +1 904 953 2000
Fax: +1 904 953 2315
Email: perez.edith@mayo.edu

Summary:

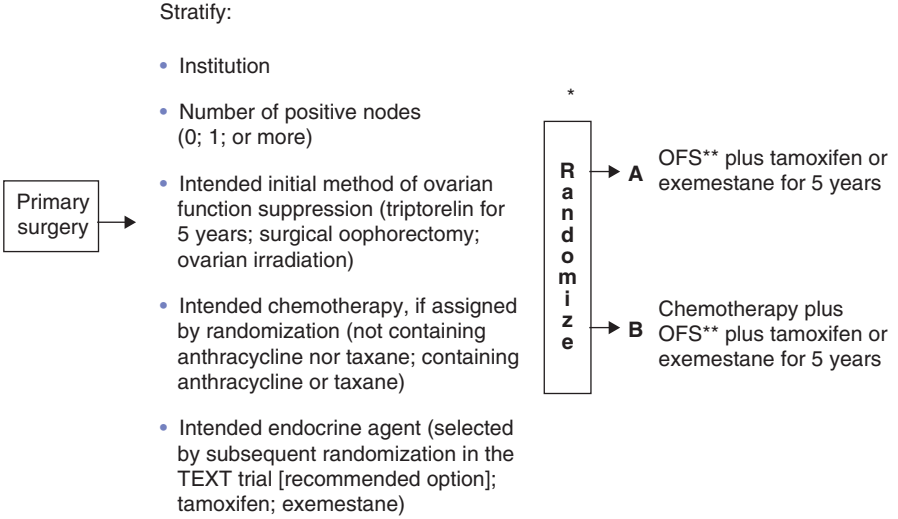
- Date of activation: August 2003
- Target accrual: 1750 patients

Objectives:

- To evaluate the role of chemotherapy as adjuvant therapy for premenopausal women with endocrine-responsive breast cancer who receive endocrine therapy.
- To assess quality of life.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Scheme:



*Randomization prior to receiving any adjuvant systemic therapy
**OFS = ovarian function suppression (triptorelin for 5 years OR surgical oophorectomy OR ovarian irradiation)

Update:

- Amendment 1: October 2005.

Related Publications:

Dellapasqua S, Castiglione-Gertsch M. The choice of systemic adjuvant therapy in receptor-positive early breast cancer. *Eur J Cancer* 2005; 41: 357–364 (commentary).

Dellapasqua S, Colleoni M, Gelber RD, Goldhirsch A. Adjuvant endocrine therapy for premenopausal women with early breast cancer. *J Clin Oncol* 2005; 23: 1736–1750 (commentary).

Price KN, Goldhirsch A for the IBCSG. Clinical trial update: International Breast Cancer Study Group. *Breast Cancer Res* 2005; 7: 252–254 (commentary).

Topics:

- Aromatase inhibitors
- Hormone-receptor-positive breast cancer
- Ovarian function suppression
- Premenopausal patients
- Tamoxifen
- Treatment tailoring
- Young patients

Keywords: Endocrine-responsive breast cancer, ovarian function suppression, chemotherapy, tamoxifen, exemestane, tailored treatment, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Chemotherapy for radically resected loco-regional relapse.
BIG 1-02/IBCSG Trial 27–02/NSABP Protocol B-37

Coordinator(s):

BIG:
S. Aebi
Institute of Medical Oncology
Inselspital
CH-3010 BERN
SWITZERLAND
Tel: +41 31 632 4114
Fax: +41 31 382 1237
Email: stefan.aebi@insel.ch

NSABP:
I. Wapnir
Stanford University Medical Center
300 Pasteur Drive H-3625
STANFORD, CA 94305-1353
USA
Tel: +1 650 736 13 53
Fax: +1 650 736 16 63
Email: Irene.wapnir@standford.edu

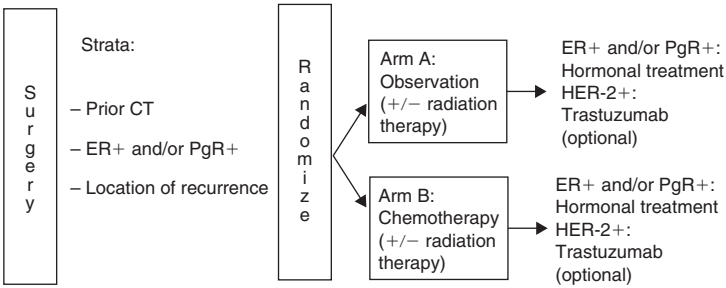
Summary:

- Date of activation: July 2002
- Target accrual: 977 patients

Objective:

- To evaluate the efficacy of adjuvant chemotherapy after radical local treatment of a first loco-regional recurrence of breast cancer.

Scheme:



https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Update:	• Amendment 1 released December 2004.
Related Publications:	None available
Topics:	• Loco-regional relapse
Keywords:	Breast cancer, loco-regional relapse, chemotherapy, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

Title: Chemotherapy adjuvant study for women at advanced Age (CASA) Phase III trial evaluating the role of adjuvant pegylated liposomal doxorubicin (PLD) for women (age 66 years or older) with endocrine non-responsive breast cancer who are not suitable for being offered a "standard chemotherapy regimen".
BIG 1–05/IBCSG Trial 32–05

Coordinator(s):

D. Crivellari
Centro di Riferimento Oncologico
Via Pedemontana Occidentale 12
I-33081 AVIANO
ITALY
Tel: +39 0434 659 653
Fax: +39 0434 652 182
Email: dcrivellari@cro.it

S. Dellapasqua
European Institute of Oncology, EIO
Unit of Research in Medical Senology
Department of Medicine
Via Ripamonti 435
I-20141 MILANO
ITALY
Tel: +39 02 57489 482
Fax: +39 02 57489 581
Email: silvia.dellapasqua@ieo.it

A. Hamilton
MBBS FRACP, Medical Oncologist
Sydney Cancer Centre
Royal Prince Alfred Hospital
Missenden Rd, Camperdown
SYDNEY 2050
AUSTRALIA
Tel: +61 2 9515 5894
Fax: +61 2 9519 1546
Email: anne.hamilton@cs.nsw.gov.au

Summary:

- Date of activation: August 2005
- Target accrual: 1296 patients

Objectives:

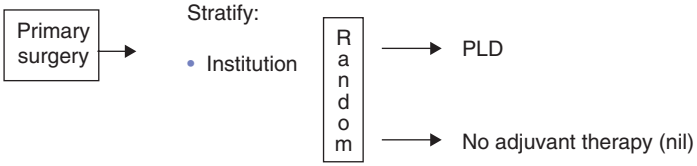
- To investigate the role of PLD as adjuvant chemotherapy for older postmenopausal women for whom chemotherapy is indicated, but standard regimens, derived from trials in younger women, are assumed to be too toxic or inconvenient.

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press

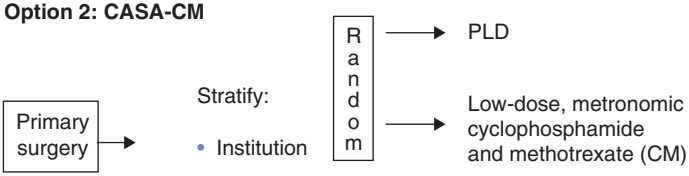
- To evaluate quality of life.
- The randomization options enable physicians and patients to choose which control group is appropriate for a given patient.

Scheme:

Option 1: CASA-nil



Option 2: CASA-CM



Update: None available

Related Publications: Price KN, Goldhirsch A for the IBCSG. Clinical trial update: International Breast Cancer Study Group. *Breast Cancer Res* 2005; 7: 252–254 (commentary).

Topics:

- Anthracyclines
- Elderly patients
- Hormone-receptor-negative breast cancer
- Low-dose chemotherapy
- Postmenopausal patients

Keywords: Endocrine non-responsive breast cancer, elderly patients (aged 66 years and older), pegylated liposomal doxorubicin, low-dose metronomic CM, quality of life

https://doi.org/10.1017/S1470903106009229 Published online by Cambridge University Press