BOOG

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Title: An open label randomized (inter)national multicenter comparative trial of 5 years adjuvant endocrine therapy with an LHRH agonist plus an aromatase inhibitor (goserelin + anastrozole) versus five courses FE90C chemotherapy followed by the same endocrine therapy in pre- or perimenopausal patients with hormone receptor-positive primary breast cancer (PRemenopausal Optimal Management IS Endocrine therapy).
BOOG 2002-01/PROMISE
ISRCTN23561723

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Summary: *Primary Objective:*

- *Relapse-free survival (RFS)*: Compare immediate optimal endocrine adjuvant therapy (goserelin + anastrozole) with standard chemotherapy followed by the same optimal endocrine treatment in terms of time to recurrence of breast cancer (defined as the earliest local recurrence, new primary breast cancer, or death).

Secondary Objectives:

- overall survival (os), the incidence of contralateral breast cancer;
- safety and long-term tolerability of both treatment regimens.

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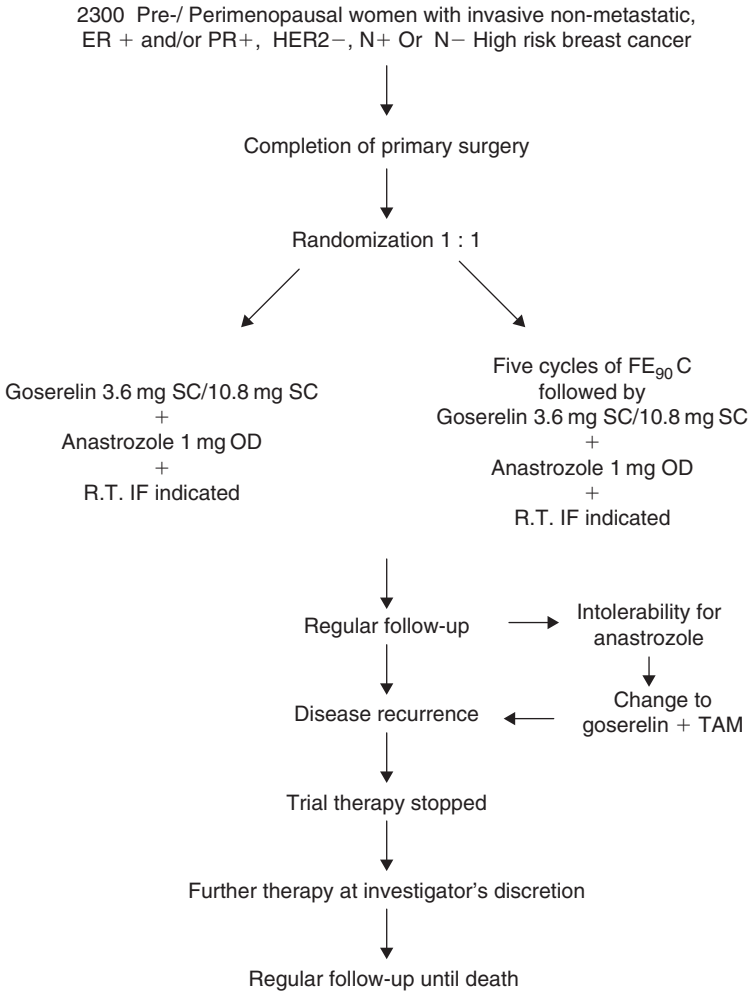
Scheme:

Hormonal treatment (goserelin, anastrozole) will be given for 5 years or until confirmed 1st recurrence.

Study design



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Update:

- Target accrual: Approximately 2300 patients.
- Start date: 1 July 2005.
- 1st amendment November 2005, 2nd amendment March 2006.
- Exclusion Her2+ patients, N+ : six courses TAC instead of five courses FE90C chemotherapy, longer accrual period.

Related Publications: None available

Topics:

- Hormonal therapy
- Pre-/perimenopausal patients
- Hormone receptor positive breast cancer
- HER2 negative patients

Keywords: None available

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Title: Open label, comparative, randomized, multicenter, study of trastuzumab (Herceptin) given with docetaxel (Taxotere) *versus* sequential single agent therapy with trastuzumab followed by docetaxel as first-line treatment for metastatic breast cancer (MBC) patients with HER2neu overexpression.
BOOG 2002-02/HERTAX
ISRCTN13770586

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Summary: *Indication:*

Patients with MBC with HER2*neu* overexpression (3^+ assessed by IHC DAKO HercepTest), previously untreated by chemotherapy, except for neoadjuvant or adjuvant (non-taxane containing) chemotherapy.

Primary Endpoints:

Progression free survival, which is defined as follows:

- In the combination treatment arm: the time from start of treatment to progression or death, whichever occurs first.
- In the treatment arm with Herceptin (H) followed by Taxotere (TXT): the time from start of H treatment till progression during subsequent TXT treatment or death whichever occurs first.
- If a patient does not receive TXT once the patient progresses on or after H alone, for whatever reason, the time to progression is taken as the time to progression on or after H.
- If a patient goes off protocol treatment and receives off protocol any other hormonal treatment or chemotherapy without previous formal assessment of progression, the date of start of that other treatment is taken as the time of progression for the purpose of this study.

Secondary Endpoints:

- Response rate. In the H followed by TXT arm, both the response on H and the response on TXT will be assessed.
- Overall survival measured from start of protocol treatment till date of death.

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Scheme: None available

Update:
- Started February 2003.

Related Publications: None available

Topics:
- HER2 positive patients
- MBC
- Taxanes
- Trastuzumab

Keywords: None available

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Title: Micro-metastases and Isolated tumour cells: Robust and Relevant Or Rubbish? The MIRROR study in BREAST CANCER.

BOOG 2003-03/ZonMW 3214

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Summary: Comparative follow-up cohort study:

- *Cohort 1*: 1000 patients with no axillary metastases and NO adjuvant systemic therapy.
- *Cohort 2*: 1000 patients with small metastases and NO adjuvant systemic therapy.
- *Cohort 3*: 1000 patients with small metastases WITH adjuvant systemic therapy.

Comparison of the three cohorts will provide us evidence whether the intensive program is effective. In fact, the intervention of the pathologist is being evaluated, that is, the intensive examination of the SN by serial sectioning and/or immunohistochemistry, which determines the subsequent clinical interventions:

- *Cohort 1 versus 2*: The prognostic relevance of small metastases (relevance of changed pathology procedure).
- *Cohort 2 versus 3*: To assess the impact of adjuvant therapy on disease-free survival.
- *Cohort 1 + 2 versus 3*: Impact of the overall program (for Cohort 3: delivery of adjuvant therapy and examinations for toxicities of

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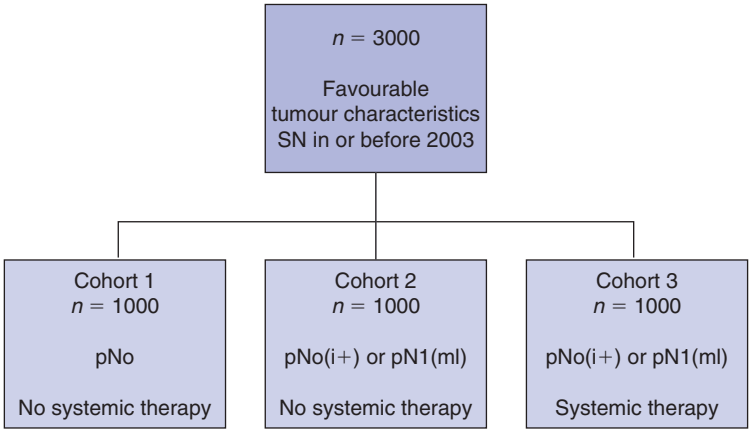
Scheme:



adjuvant therapies; but, possibly less examinations for distant metastases).

Update:

- Start 1 January 2006.

Related Publications: None available

Topics:

- Sentinel node micrometastasis

Keywords: None available

https://doi.org/10.1017/S1470903106009060 Published online by Cambridge University Press

Title: Radiation dose intensity study in breast cancer in young women: a randomized phase III trial of additional dose to the tumor bed.
BOOG 2004-01/Young Boost
SRCTN45066831

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Summary:

Hypothesis:

Will 10 Gy additional boost to the tumor bed yield an increase in local control at 10 years from 88% to 93%, with still acceptable cosmesis for breast cancer patients less than 51 years?

Primary Outcome:

- Local control at 10 year.

Secondary Outcome:

- Cosmetic outcome.

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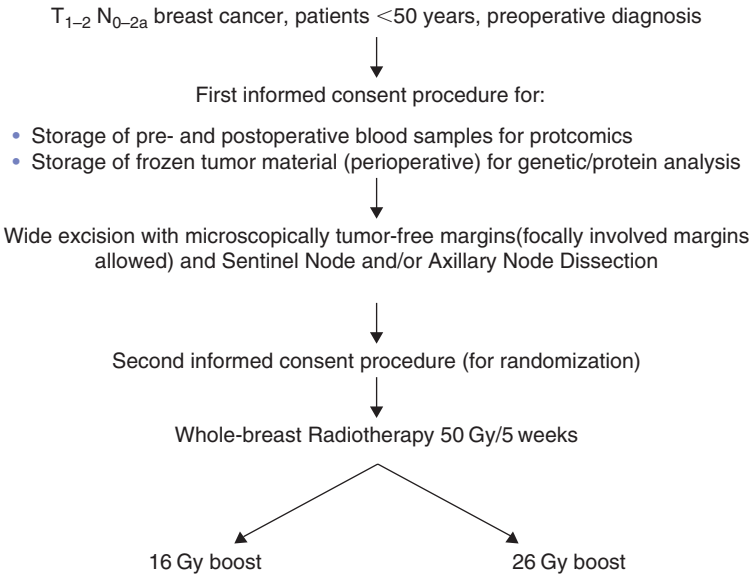
Additional Objectives:

- **A**: To test the genotypic and phenotypic profiles of breast tumors [van de Vijver *et al.*, 2002] in young patients with invasive breast cancer, and its relation to:
  - local recurrence after BCT,
  - lymph node metastases,
  - distant metastases and surviva,
  - radiosensitivity,
  - age.
- **B**: To determine whether improved genotypic and phenotypic profiles can be determined related to the endpoints mentioned in **A**.

Scheme:



Update:

- Start: 1 July 2004; Expected closing: 1 July 2009.

Related Publications:

van de Vijver MJ, He YD, van't Veer LJ *et al.* A gene-expression signature as a predictor of survival in breast cancer. *N Eng J Med* 2002; 347: 1999–2009.

Topics:

- Loco-regional relapse
- Radiotherapy
- Young patients

Keywords:

Gene expression profile, radiotherapeutic boost

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Title: Microarray analysis in breast cancer to Tailor Adjuvant Drugs Or Regimens, a randomized phase III study.
MATADOR, BOOG 2005-02, CKTO 2004-04
ISRCTN61893718

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Summary: *Primary Objective:*

- To define gene expression profiles that can predict a disease-free survival advantage for either dose dense therapy, or docetaxel – containing chemotherapy.

Secondary Objectives:

- To define gene expression profiles that can predict a recurrence-free survival advantage for either dose dense therapy, or docetaxel – containing chemotherapy.
- Is TAC better than AC dd concerning DFS, RFS, breast cancer specific survival and all cause survival?

This is a prospective, non-blinded randomized phase II/III trial. A phase II feasibility study will be performed to assess accrual rate and sample collection efficiency. In the case of an accrual rate of less than 60 patients/year, the study may be stopped. Before surgery patients will be asked permission to collect tumor tissue and blood serum for possible research in the future related to their breast cancer. Only patients who appear to have node positive disease after surgery will be asked to participate in the current study. After informed consent has been obtained, they will be randomized to one of the chemotherapy arms (TAC or AC dd). Patients will be stratified according to treatment center, menopausal status (pre *versus* post), type of surgery (mastectomy *versus* lumpectomy), hormone receptor status (ER and/or PR+ *versus* both negative), HER2 receptor status, nodal status (pN1(sn) (e.g. AMAROS study), pN1–3 *versus* pN4+), tumor size (pT0 + 1 *versus* pT2 *versus* pT3), and sequence of chemotherapy–radiotherapy (chemotherapy followed by radiotherapy or vice versa). At a later stage all pathology data will be reviewed centrally.

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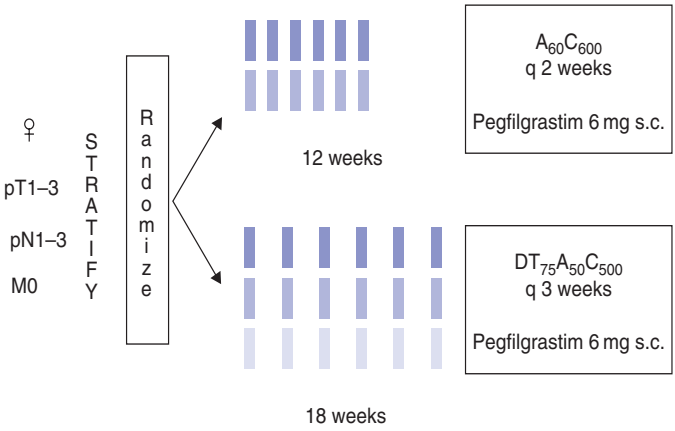
Scheme:



Update:

- Enrollment start: April 2004.
- Enrollment stop: April 2008 (1200 pts).

Related Publications: None available

Topics:

- Anthracyclines
- Dose densification
- Node positive breast cancer
- Taxanes

Keywords: Gene expression profile

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Title: A prospective randomised, open, multicentre, phase III study to assess different Durations of Anastrozole therapy after 2–3 years Tamoxifen as Adjuvant therapy in postmenopausal women with breast cancer.
2006-01/DATA

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Summary: Approximately 2000 postmenopausal female patients with hormone receptor positive breast cancer already receiving 2–3 years adjuvant tamoxifen therapy.

Primary Objective:

- To assess the efficacy of 6 to 5 years of anastrozole compared with 3 to 2 years anastrozole after 2–3 years adjuvant tamoxifen, measured as Disease Free Survival (DFS).

Secondary Objectives:

- To determine if there is a difference in outcome between patients with node positive or node negative disease at the time of diagnosis (DFS).
- To determine if there is a difference in outcome between patients with ER+PgR− disease or patients with ER+PgR+ disease (DFS).
- To determine if there is a difference in outcome between patients with Her2neu negative disease or Her2neu positive disease (DFS).
- To determine if there is a difference in incidence of contralateral breast cancer in the two groups.
- To demonstrate an improvement in OS after 6 to 5 years of adjuvant treatment with anastrozole as compared with 3 to 2 years anastrozole in patients that already received 2–3 years adjuvant tamoxifen (OS).

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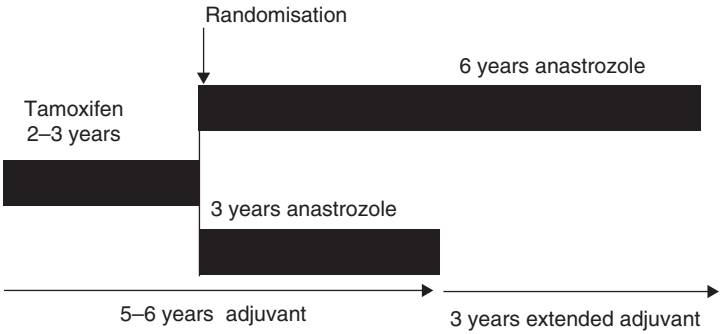
Scheme:



Update:

- Proposed start: June 2006.

Related Publications: None available

Topics:

- Aromatase inhibitors
- Tamoxifen
- Hormone receptor positive breast cancer

Keywords: None available

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Title: A randomized, open-label phase III study of first line chemotherapy in elderly metastatic breast cancer patients, comparing intravenous pegylated liposomal doxorubicin with oral capecitabine; and the incorporation of a complete geriatric assessment.
2006-02/OMEGA

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Summary: Female patients with metastatic breast cancer, being 65 years or older, who are eligible for first line chemotherapy will be randomized between pegylated liposomal doxorubicin (PEG doxo, 45 mg/m^2) (given intravenously, each 28 days), and capecitabine (2000 mg/m^2, days 1–14, to be repeated every 21 days).
Questionnaires regarding quality of life (QoL) and a geriatric assessment tool (GA) will be incorporated to further investigate the contribution and role of these types of assessments aiming to improve the clinical evaluation

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of the condition and/or frailty of the individual patient and QoL during chemotherapy in elderly metastatic breast cancer patients.

Primary Objective:

- Progression free survival (PFS)

Secondary Objectives:

- Objective response rate (complete responses (CR) + partial responses (PR)), in the two treatment regimens.
- Clinical benefit (CB) rate (summation of CR + PR + stable disease (SD) $\geqslant$ 24 weeks) in the two treatment regimens.
- Overall survival (OS) in the two treatment groups.
- Relation of response and toxicity of the respective chemotherapy regimen with co-morbidity and co-medication.
- The value of geriatric assessments.
- Toxicity and tolerability of the two regimens.
- Compliance of the two regimens.

Scheme:

This is a randomized, open-label, multicenter study comparing PEG doxorubicin (CAELYX) with capecitabine (Xeloda) as first line chemotherapy in MBC patients being 65 years or older.

Patients will be randomized to one of two treatment regimens:

Group 1: PEG doxorubicin 45 mg/m^2, administered intravenously every 28 days, until progression, unacceptable toxicity OR six cycles (6 months of therapy).
Group 2: Capecitabine, administered at a dosage of 1000 mg/m^2, taken orally and twice daily (BID) for 14 consecutive days followed by a 7-day rest period. A subsequent cycle is repeated after 21 days. Therapy is continued until progressive disease, unacceptable toxicity OR eight cycles (6 months of therapy).

Update:

- Start: 1 June 2006.

Related Publications:

None available

Topics:

- Capecitabine
- Elderly patients
- Postmenopausal patients

Keywords:

Capecitabine, Caelyx, elderly patients, geriatric assessment

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Title: *BOOG participation in International studies:*

BOOG 2001-01/TEAM trial
BOOG 2001-02/AMAROS (EORTC 10981/22023)
BOOG 2002-04/HERA (BIG 1-01/EORTC 10011/BO16348B)
BOOG 2003-02 (BIG 1-02/IBCSG 27-02)
BOOG 2003-04 (GBG 29)
BOOG 2004-02/TBP (GBG 26, BIG 3-05)
BOOG 2005-01/CASA (IBCSG 32-05/BIG 1-05)
BOOG 2005-03/MINDACT (EORTC 10041, BIG 3-04)
BOOG 2006-03/SUPREMO (BIG 2-04)
BOOG 2006-04/Adjuvant lapatinib study (BIG 2-06/EGF106708)

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