

IBIS-II

Country: International

Group: International Breast Cancer Intervention Study II Group
(IBIS-II)

Co-Chairs: J. Cuzick
Cancer Research UK Centre for Epidemiology, Mathematics and Statistics
Wolfson Institute of Preventive Medicine
Charterhouse Square
LONDON EC1M 6BQ
UNITED KINGDOM
Tel: +44 207 014 0226
Fax: +44 207 014 0269
Email: jack.cuzick@cancer.org.uk

J.F. Forbes
Department of Surgical Oncology
University of Newcastle
Newcastle Mater Misericordiae Hospital
Locked bag 7
Hunter Region Mail Centre, NSW 2310
AUSTRALIA
Tel: +61 2 4921 1155
Fax: +61 2 4929 1966
Email: john.forbes@anzbctg.newcastle.edu.au

A. Howell
CRC Medical Oncology
Christie Hospital
Wilmslow Road
Winthinton
MANCHESTER M20 4BX
UNITED KINGDOM
Tel: +44 161 446 8037
Fax: +44 161 446 8000/3299
Email: maria.parker@christie-tr.nwest.nhs.uk

Trial Office: IBIS-II
Cancer Research UK Centre for Epidemiology, Mathematics and Statistics
Wolfson Institute of Preventive Medicine
Charterhouse Square
LONDON EC1M 6BQ
UNITED KINGDOM
Tel: +44 (0) 20 7014 0236
Fax: +44 (0) 20 7014 0248
Email: ibis@cancer.org.uk

Website: www.ibis-trials.org

Title: An international multi-centre study of anastrozole *versus* placebo in postmenopausal women at increased risk of breast cancer. IBIS-II (Prevention).
BIG 05-02a

Coordinator(s): J. Cuzick
Cancer Research UK Centre for Epidemiology,
Mathematics and Statistics
Wolfson Institute of Preventive Medicine
Charterhouse Square
LONDON EC1M 6BQ
UNITED KINGDOM
Tel: +44 207 014 0226
Fax: +44 207 014 0269
Email: jack.cuzick@cancer.org.uk

J.F. Forbes
Department of Surgical Oncology
University of Newcastle
Newcastle Mater Misericordiae Hospital
Locked bag 7
Hunter Region Mail Centre, NSW 2310
AUSTRALIA
Tel: +61 2 4921 1155
Fax: +61 2 4929 1966
Email: john.forbes@anzbctg.newcastle.edu.au

A. Howell
CRC Medical Oncology
Christie Hospital
Wilmslow Road
Winthinton
MANCHESTER M20 4BX
UNITED KINGDOM
Tel: +44 161 446 8037
Fax: +44 161 446 8000/3299
Email: maria.parker@christie-tr.nwest.nhs.uk

Summary:

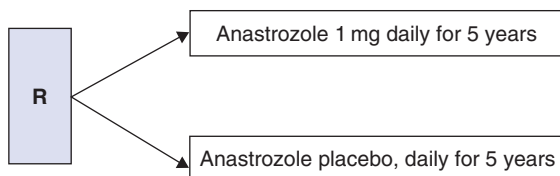
- Opened in Spring 2003
- Target accrual: 6000

Primary Objective:

- To determine if anastrozole is effective in preventing breast cancer in postmenopausal women at increased risk of the disease.

Secondary Objectives:

- To examine the role of anastrozole in preventing oestrogen receptor positive breast cancer.
- To examine the effect of anastrozole on breast cancer mortality.
- To examine the effect of anastrozole on other cancers, cardiovascular disease, fracture rates, and non-breast cancer deaths.
- To examine tolerability and acceptability of side effects experienced by women on the study.

Scheme:**Update:**

- As of October 2006, 1241 participants have been randomised in the Prevention stratum and 164 international sites are actively recruiting in the trial.

Related Publications:

Cuzick J. Aromatase inhibitors for breast cancer prevention. *J Clin Oncol* 2005; 23: 1636–1643.

Topics:

- Aromatase inhibitors
- Bisphosphonates
- Blood markers
- Predictive markers
- Bone mineral density
- Hormonal therapy
- Hormone replacement therapy
- Postmenopausal patients
- Prevention

Keywords:

Prevention, breast cancer, family history, anastrozole, aromatase inhibitors, bone density

Title: An international multi-centre study of tamoxifen *versus* anastrozole in postmenopausal women with ductal carcinoma *in situ*. IBIS-II. BIG 05-02b

Coordinator(s): J. Cuzick
Cancer Research UK Centre for Epidemiology, Mathematics and Statistics
Wolfson Institute of Preventive Medicine
Charterhouse Square
LONDON EC1M 6BQ
UNITED KINGDOM
Tel: +44 207 014 0226
Fax: +44 207 014 0269
Email: jack.cuzick@cancer.org.uk

J.F. Forbes
Department of Surgical Oncology
University of Newcastle
Newcastle Mater Misericordiae Hospital
Locked bag 7
Hunter Region Mail Centre, NSW 2310
AUSTRALIA
Tel: +61 2 4921 1155
Fax: +61 2 4929 1966
Email: john.forbes@anzbctg.newcastle.edu.au

A. Howell
CRC Medical Oncology
Christie Hospital
Wilmslow Road
Winthinton
MANCHESTER M20 4BX
UNITED KINGDOM
Tel: +44 161 446 8037
Fax: +44 161 446 8000/3299
Email: maria.parker@christie-tr.nwest.nhs.uk

Summary:

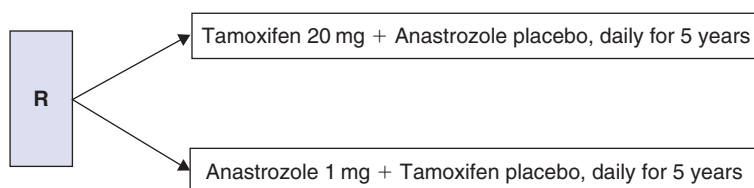
- Opened in Spring 2003
- Target accrual: 4000

Primary Objectives:

- To determine if anastrozole is at least as effective as tamoxifen in local control and prevention of contralateral disease in women with locally excised oestrogen (ER) or progesterone (PgR) positive ductal carcinoma *in situ* (ER or PgR +ve DCIS).

Secondary Objectives-II:

- To compare the effectiveness of tamoxifen and anastrozole according to the receptor status of the primary or recurrent cancer.
- To examine the rate of breast cancer recurrence and new contralateral tumours after cessation of tamoxifen or anastrozole.
- To examine the effect of tamoxifen *versus* anastrozole on breast cancer mortality.
- To examine the effect of tamoxifen and anastrozole on other cancers, cardiovascular disease, fracture rates, and non-breast cancer deaths.
- To examine tolerability and acceptability of side effects experienced by women on the study.

Scheme:**Update:**

- Opened in Spring 2003. As of October 2006, 776 participants have been randomised in the DCIS stratum and 164 international sites are actively recruiting in the trial.

Related Publications:

Cuzick J. Treatment of DCIS – results from clinical trials, *Surgical Oncology* 2003; 12: 213–219.

Topics

- DCIS
- Hormone receptor positive breast cancer
- Tamoxifen
- Tamoxifen duration
- Aromatase inhibitors
- Blood markers
- Predictive markers
- Hormonal therapy
- Hormone replacement therapy
- Postmenopausal patients
- Prevention

Keywords:

Prevention, DCIS, breast cancer, family history, anastrozole, aromatase inhibitors, tamoxifen, recurrence