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An international multi-centre trial of tamoxifen versus anastrozole in postmenopausal women who have had a recent hormone receptor positive Ductal Carcinoma In Situ (DCIS)

Submission date
07/01/2005

Recruitment status
No longer recruiting

Registration date
26/04/2005

Overall study status
Completed

Last Edited
24/04/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-tamoxifen-or-anastrozole-in-postmenopausal-women-with-ductal-carcinoma-in-situ-of-the-breast

Study website
http://www.ibis-trials.org/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
2004-003992-35

IRAS number

ClinicalTrials.gov number
NCT00072462

Secondary identifying numbers
N/A

Study information

Scientific Title
An international multi-centre trial of tamoxifen versus anastrozole in postmenopausal women who have had a recent hormone receptor positive, Ductal Carcinoma In Situ (DCIS)

Acronym
IBIS-II DCIS

Study objectives
Primary hypotheses:
1. To determine if anastrozole is at least as effective as tamoxifen in local control and prevention of contralateral disease in women with locally excised Estrogen Receptor (ER) or Progesterone Receptor (PgR) positive DCIS.
2. To compare side effect profiles of tamoxifen and anastrozole.

Secondary hypotheses:
1. To compare the effectiveness of tamoxifen and anastrozole according to the receptor status of the primary or recurrent cancer.
2. To examine the rate of breast cancer occurrence after cessation of tamoxifen or anastrozole.
3. To examine the effect of tamoxifen versus anastrozole on breast cancer mortality.

4. To examine the effect of tamoxifen and anastrozole on other cancers, cardiovascular disease, fracture rates, and non-breast cancer deaths.
5. To examine the tolerability and acceptability of side effects experienced by women on the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study has been approved by the North West MREC (Multi-centre Research Ethics Committee) and local ethics committees (LREC).

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No longer available

Health condition(s) or problem(s) studied
Breast cancer

Interventions
IBIS-II DCIS is a randomised double blind study investigating the use of anastrozole versus tamoxifen in women who have had a recent hormone receptor positive, locally excised DCIS lesion. There are two treatment groups:
Group A: tamoxifen 20 mg and anastrozole placebo
Group B. tamoxifen placebo and anastrozole 1 mg
Each patient will take the two tablets once a day for the next 5 years.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Tamoxifen, anastrozole

Primary outcome measure

All new and recurrent breast cancer

Secondary outcome measures
1. Breast cancer mortality
2. Thromboembolic events
3. Cardiovascular events
4. Osteoporosis
5. Other relevant side effects

Overall study start date
25/05/2003

Completion date
31/05/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/02/2012:
1. All women must be postmenopausal and between the ages of 40 and 70 years.
Postmenopausal status is defined as meeting one or more of the following criteria:
1.1. Over the age of 60 years
1.2. Bilateral oophorectomy
1.3. Aged 60 years or under with a uterus and amenorrhoea for at least 12 months
1.4. Aged 60 years or under without a uterus and with Follicle-Stimulating Hormone (FSH) more than 30 IU/L
2. Women with locally excised Oestrogen Receptor (ER) positive DCIS excised within 6 months (ER or PR status must be greater than or equal to 5% positive cells)
3. A baseline bone mineral density scan within the last two years (dual-energy X-ray absorptiometry [DXA] either of hip, lumbar spine, forearm) and spinal X-ray will be required for all women
4. A fully informed signed consent form must have been obtained
5. Women who have had Lobular carcinoma in situ.
6. Women who have had Atypical hyperplasia in a benign lesion.
7. A bilateral mammogram must have been taken within the last year.
8. Women must be accessible for treatment and follow-up. Participants randomised in this trial must be treated and followed via a participating institution.

Previous inclusion criteria:
1. All women must be postmenopausal and between the ages of 40 and 70 years.
Postmenopausal status is defined as meeting one or more of the following criteria:
1.1. Over the age of 60 years
1.2. Bilateral oophorectomy
1.3. Aged 60 years or under with a uterus and amenorrhoea for at least 12 months
1.4. Aged 60 years or under without a uterus and with Follicle-Stimulating Hormone (FSH) more than 30 IU/L
2. Women with locally excised Oestrogen Receptor (ER) positive DCIS diagnosed within the last 6 months in which there are tumour free margins of at least 1 mm
3. A baseline bone mineral density scan within the last two years (dual-energy X-ray

absorptiometry [DXA] either of hip, lumbar spine, forearm) and spinal X-ray will be required for all women
4. A fully informed signed consent form must have been obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
Target: 4000. Final: 2980.

Total final enrolment
2980

Key exclusion criteria
Current exclusion criteria as of 23/02/2012:
1. Have had (or are planning to have) their breast removed (a mastectomy)
2. Have had tamoxifen or raloxifene for more than 6 months in the last 5 years
3. Have had any other cancer in the last 5 years (except non-melanoma skin cancer or carcinoma in situ of the cervix)
4. Are taking medication to thin the blood
5. Have had a stroke
6. Have osteoporosis and fractures of the spine (if this applies, they may be able to take part - the trial doctor will assess each person on an individual basis)
7. Have any other serious medical condition
8. Have been taking part in any other clinical trial within the last 3 months
9. Any previous breast cancer at any age
10. Life expectancy of less than 10 years or any other medical condition that would significantly interfere with the ability to accept the chemopreventive treatment

Previous exclusion criteria:
1. Have had (or are planning to have) their breast removed (a mastectomy)
2. Have had tamoxifen, raloxifene or other Selective Estrogen Receptor Modulators (SERMs) for more than 3 months in the past
3. Have had any other cancer in the last 5 years (except non-melanoma skin cancer or carcinoma in situ of the cervix)
4. Are taking medication to thin the blood
5. Have had a stroke
6. Have osteoporosis and fractures of the spine (if this applies, they may be able to take part - the trial doctor will assess each person on an individual basis)

7. Have any other serious medical condition
8. Have been taking part in any other clinical trial within the last 3 months

Date of first enrolment
25/05/2003

Date of final enrolment
31/01/2012

Locations

Countries of recruitment
Australia

Austria

Belgium

Chile

England

Finland

France

Germany

Hungary

India

Ireland

Italy

Malta

New Zealand

Sweden

Switzerland

Türkiye

United Kingdom

Study participating centre

Wolfson Institute of Preventive Medicine
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Sponsor information

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Sponsor type
University/education

Website
http://www.jrmo.org.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The initial results were published in 2014, the next major analysis was completed in 2020 and will be published in 2021. The final analysis for the purpose of the CSR will be uploaded within 12 months of the global EoT (31/05/2021). The long-term follow-up for this cohort is now conducted on a new protocol (IRAS 258590, REC 19/LO/0984, registration pending).

Intention to publish date

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	decision aid sub-study results	01/09/2008		Yes	No
Results article	results	27/02/2016		Yes	No
Results article	adherence results	01/02/2018		Yes	No