

# 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	Recruitment status	<input type="checkbox"/> Prospectively registered
07/01/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
26/04/2005	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
24/04/2025	Cancer	

## 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>

## Contact information

### Type(s)

Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2004-003992-35

**ClinicalTrials.gov (NCT)**  
NCT00072462

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

All new and recurrent breast cancer

## **Key secondary outcome(s))**

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

## **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

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

40 years

## **Upper age limit**

70 years

**Sex**

Female

**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**

United Kingdom

England

Australia

Austria

Belgium

Chile

Finland

France

Germany

Hungary

India

Ireland

Italy

Malta

New Zealand

Sweden

Switzerland

Türkiye

#### **Study participating centre**

**Wolfson Institute of Preventive Medicine**  
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## **Sponsor information**

#### **Organisation**

Queen Mary University of London (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, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**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?
<a href="#">Results article</a>	decision aid sub-study results	01/09/2008		Yes	No
<a href="#">Results article</a>	results	27/02/2016		Yes	No
<a href="#">Results article</a>	adherence results	01/02/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes