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# IBIS-II-O: Observational long-term follow up study of participants from the IBIS-II DCIS and Prevention clinical trials of drugs for breast cancer prevention

**Submission date**
14/10/2021

**Recruitment status**
Recruiting

**Registration date**
15/11/2021

**Overall study status**
Ongoing

**Last Edited**
09/04/2024

**Condition category**
Cancer

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
The IBIS-II-O study tracks the long-term medical outcomes of 3000 + UK women who took part in the main IBIS-II clinical trials (Prevention [ISRCTN31488319], DCIS [ISRCTN37546358]) between 2004 and 2021. These studies looked at the breast cancer-preventive effect of anastrozole in women at increased risk of breast cancer. The women either took anastrozole compared with either tamoxifen (IBIS-II DCIS) or anastrozole compared with a placebo (IBIS-II Prevention) for 5 years and were then followed up for a further 5 years.

Results of IBIS-II DCIS and Prevention show that anastrozole significantly reduces the risk of developing breast cancer in these groups and that the effect continues for many years afterwards. IBIS-II-O uses data from NHS digital to track incidences of new and recurrent breast cancers, other cancers, deaths plus known side effects of anastrozole to continue to measure the long-term effects of anastrozole in these women.

Who can participate?
As this study follows an existing cohort there is no additional recruitment.

What does the study involve?
Long-term follow-up of the IBIS-II DCIS and Prevention cohorts via NHS Digital.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Queen Mary University of London

When is the study starting and how long is it expected to run for?
July 2018 to June 2026

Who is funding the study?
AstraZeneca (UK)

Who is the main contact?
Barts Clinical Trials Unit, bartsctu@qmul.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Dr Barts Clinical Trials Unit

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# Additional identifiers

### Integrated Research Application System (IRAS)
258590

# Study information

### Scientific Title
Observational long-term follow up study of participants from the IBIS-II DCIS and Prevention clinical trials

### Acronym
IBIS-II-O

### Study objectives
Long-term follow up of participants from the IBIS-II studies (Prevention and DCIS) to understand long term benefits and risks of anastrozole;
Prevention cohort: To determine if anastrozole is effective in preventing long-term breast cancer in postmenopausal women at increased risk of the disease.
Ductal Carcinoma in Situ (DCIS) cohort: To determine if anastrozole is at least as effective as tamoxifen in long-term local control and prevention of contralateral disease in women with locally excised ER or PgR positive DCIS.

### Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 30/07/2019, London - Fulham Research Ethics Committee (Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8084, (0)207 104 8286; fulham.rec@hra.nhs.uk), ref: 19/LO/0984

## Study design
Observational cohort study

## Primary study design
Observational

## Study type(s)
Prevention

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

## Interventions
Current interventions as of 09/04/2024:
Long-term follow-up study of the IBIS-II DCIS (NCT00072462; ISRCTN37546358) and Prevention (NCT00078832; ISRCTN31488319) cohorts via NHS Digital.
Data linked to the participants of the IBIS-II studies will be extracted annually from NHS Digital providing HES, Civil registration, and Cancer Registry datasets. This data will be analysed with existing IBIS-II data to identify new or recurrent breast cancers, other cancers, and cardiovascular and musculoskeletal events to understand the long-term effects of anastrozole in women with an increased risk of breast cancer. Follow-up is to continue until 2026, although the study may be extended.

Previous interventions:
Long-term follow-up study of the IBIS-II DCIS and Prevention cohorts via NHS Digital.
Data linked to the participants of the IBIS-II studies will be extracted annually from NHS digital providing HES, Civil registration, and Cancer Registry datasets. This data will be analysed with existing IBIS-II data to identify new or recurrent breast cancers, other cancers, cardiovascular and musculoskeletal events to understand the long-term effects of anastrozole in women with an increased risk of breast cancer. Follow-up to continue until 2026, although the study may be extended.

## Intervention Type
Other

## Primary outcome(s)
Measured at the end of the study:
1. IBIS-II Prevention cohort: incidence of breast cancer measured via data from the digital registry or local pathology report with histologically confirmed breast cancer, both invasive and non-invasive (i.e. including DCIS) when registry data is not sufficient
2. IBIS-II DCIS cohort: incidence of breast cancer measured using data from digital registry or local pathology report with histologically confirmed breast cancer, both invasive and non-invasive (i.e. including DCIS) when registry data is not sufficient.

## Key secondary outcome(s))

Measured at the end of the study:
1. IBIS-II Prevention Cohort: breast cancer mortality
2. IBIS-II DCIS Cohort: breast cancer mortality
Both measured via COD and date confirmed via data registry

### Completion date
01/06/2026

## Eligibility

### Key inclusion criteria
1. Randomised to treatment in IBIS- II Prevention or DCIS studies
2. Participant was known to be alive at the point the study closed
3. Has given valid consent to participate in compliance with local and national requirements
4. Participant's local IBIS-II study site is closed to the IBIS-II Prevention and DCIS CTIMP study protocols

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Participant death has been reported to the study during their participation in the IBIS-II Prevention and DCIS CTIMP study
2. Participant has withdrawn consent to participate in IBIS-II Prevention and DCIS CTIMP studies
3. Participant has withdrawn consent to digital registry flagging in the IBIS-II Prevention and DCIS CTIMP study
4. Participant known to have emigrated

### Date of first enrolment
01/06/2021

### Date of final enrolment
01/06/2026

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Queen Mary University of London**
327 Mile End Road
London
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E1 4NS

# Sponsor information

**Organisation**
Queen Mary University of London

**ROR**
https://ror.org/026zzn846

# Funder(s)

**Funder type**
Industry

**Funder Name**
AstraZeneca

**Alternative Name(s)**
AstraZeneca PLC, Pearl Therapeutics, AZ

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol file | version 2.0 | 11/06/2021 | 15/10/2021 | No | No |