

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/11/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact details

Wolfson Institute for Cancer Prevention
Queen Mary University
London
United Kingdom
EC1M 6BQ
+44 (0)2078823517
bartsctu@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

258590

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

No PIS for this study as cohorts consented in previous studies and were written to at the end of the main CTIMP studies

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/07/2018

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

Age group

Adult

Sex

Female

Target number of participants

3000

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**

England

United Kingdom

Study participating centre

Queen Mary University of London

327 Mile End Road

London

United Kingdom

E1 4NS

Sponsor information**Organisation**

Queen Mary University of London

Sponsor details

Joint Research Management Office (JRMO)

Research Services

Dept. W

69-89 Mile End Road

London

England

United Kingdom

E1 4UJ

+44 (0)2078823517

research.governance@qmul.ac.uk

Sponsor type

University/education

Website

<http://www.jrmo.org.uk>

ROR

<https://ror.org/026zzn846>

Funder(s)

Funder type

Industry

Funder Name

AstraZeneca

Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high impact journal.

Intention to publish date

01/06/2027

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?
Protocol file	version 2.0	11/06/2021	15/10/2021	No	No

