Study record 40544

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Title and Additional Identifiers

Submission number
40544

ISRCTN

DOI

Public title
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

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

Acronym
IBIS-II-O

EudraCT number
Nil known

ClinicalTrials.gov number
Nil known

Protocol /serial number
IRAS 258590

Condition category
Cancer

Date Applied
14/10/2021

Date Assigned

Last Edited
14/10/2021

Prospective/Retrospective

Overall Trial Status
Ongoing

Recruitment status
Recruiting

Study Information

Study hypothesis
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
Approved 21/04/2021, Fulham Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8084; fulham.rec@hra.nhs.uk), ref: 19/LO/0984

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Trial setting
Other

Trial type
Prevention

Overall trial start date
21/04/2021

Overall trial end date
01/06/2026

Overall trial status override

Reason abandoned (if study stopped)

Condition
Breast cancer prevention

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 in order 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
Drug

Phase
Not Applicable

Drug name(s)
anastrozole

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

Trial website

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

Eligibility

Participant 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
Patient

Age group
Adult

Gender
Female

Target number of participants
3000

Total final Enrolment

Participant 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

Recruitment start date
01/06/2021

Recruitment end date
01/06/2026

Recruitment status override

Locations

Countries of recruitment
United Kingdom
England

Trial participating centres

Trial Centre

Trial Centre Name
Wolfson Institute of Preventative Medicine and Institute of Population Health Sciences

Address
Queen Mary University of London
Charterhouse Square

City
London

Country
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EC1M 6BQ

Plain English Summary

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 so 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?
April 2021 to June 2026

Who is funding the study?
AstraZeneca (UK)

Who is the main contact?
Jessica Adams, j.adams@qmul.ac.uk

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal.

IPD sharing statement:
The current data sharing plans for this study are unknown and will be available at a later date.

Intention to publish date
01/06/2027

Participant level data

To be made available at a later date

Basic results (scientific)

Results (plain English)

Publication list

Publication citation(s)

Contact(s)

Contact

Type
Public

Title
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Funder

Funder Name
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Alternative Name(s)
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Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

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Payment Method

Payment method
Offline payment

Trusted funder

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9738687

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Why did you choose ISRCTN to register your trial?
Ethics committee policy