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An international multicentre study of tamoxifen versus placebo in women at increased risk of breast cancer

Submission date 24/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/06/2006	**Overall study status** Completed	
Last Edited 24/04/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.ibis-trials.org/thetrials/ibistrials/ibis-1

Study website
http://www.cptu.org.uk/trials/IBISI.php

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
2005-003091-38

IRAS number

ClinicalTrials.gov number
NCT00002644

Secondary identifying numbers
N/A

Study information

Scientific Title
An international multicentre study of tamoxifen versus placebo in women at increased risk of breast cancer

Acronym
IBIS-I

Study objectives
A study to evaluate the reduction in incidence of, and mortality from, breast cancer associated with taking tamoxifen daily for five years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The start of the IBIS I study predated the existence of Multicentre Research Ethics Committees (MREC). However, Central Office for Research Ethics Committees (COREC) have appointed the Central and South Bristol Research Ethics Committee to be the lead REC for the IBIS I study. The Central South Bristol REC reference assigned to study is E3244.

Study design

A multicentre randomized clinical trial of 7,000 women aged between 45 and 70 years who have a risk of breast cancer at least twice that of the general population

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Patient information can be found at: https://www.ibis-trials.org/thetrials/ibistrials/ibis-1

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

Interventions
Women were randomised to receive either tamoxifen 20 mg per day for 5 years or placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
The development of histologically confirmed breast cancer, both invasive and non-invasive (i.e. including ductal carcinoma in situ [DCIS]

Secondary outcome measures
Other cancers, other serious medical conditions or side effects

Overall study start date
14/04/1992

Completion date
30/03/2011

Eligibility

Key inclusion criteria

To be eligible, women must satisfy at least one of the entry criteria listed below:
1. A mammogram must have been taken within the last year indicating no malignant disease
2. A signed consent form must have been obtained

Entry criteria:
The entry criteria were based on a relative risk of at least twofold for women aged 45-70 years, fourfold for women aged 40-44 years and tenfold for women aged 35-39 years.

Age 45-70 years:
1. First-degree relative who developed breast cancer at age 50 years or less
2. First-degree relative who developed bilateral breast cancer
3. Two or more first or second-degree relatives who developed breast cancer
4. Nulliparous and a first-degree relative who developed breast cancer
5. Benign biopsy with proliferative disease and a first-degree relative who developed breast cancer
6. Lobular carcinoma in situ
7. Atypical ductal or lobular hyperplasia in a benign lesion
8. Women at high risk who do not fit into the above categories (risk equivalent)*
* These women must have clearly apparent family history indicating at least a twofold increased risk of breast cancer.

Age 40-44 years:
8. Two or more first or second-degree relatives who developed breast cancer at age 50 years or less
9. First-degree relative with bilateral breast cancer who developed the first breast cancer at age 50 years or less
10. Nulliparous and a first-degree relative who developed breast cancer at age 40 years or less
11. Benign biopsy with proliferative disease and a first-degree relative who developed breast cancer at age 40 years or less
12. Lobular carcinoma in situ
13. Atypical ductal or lobular hyperplasia in a benign lesion
14. Women at high risk who do not fit into the above categories (risk equivalent)*
* These women must have clearly apparent family history indicating at least a fourfold increased risk of breast cancer.

Age 35-39 years:
15. Two or more first-degree relatives who developed breast cancer at age 50 years or less
16. First-degree relative with bilateral breast cancer who developed the first breast cancer at age 40 years or less
17. Lobular carcinoma in situ
18. Women at high risk who do not fit into the above categories (risk equivalent)*
*These women must have clearly apparent family history indicating at least a tenfold increased risk of breast cancer.

Participant type(s)
Patient

Age group
Adult

Lower age limit

35 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
7,000

Total final enrolment
7152

Key exclusion criteria
1. Pregnant, or at pregnancy risk. If necessary, pre- and peri-menopausal women must use non-hormonal contraception during the trial
2. Any previous cancer (except non-melanoma skin cancer or in situ cancer of the cervix)
3. Life expectancy of less than 10 years or other medical condition more serious than the risk of breast cancer
4. Psychologically and physically unsuitable for 5 years tamoxifen or placebo therapy
5. Current treatment with anti-coagulants
6. Previous deep vein thrombosis or pulmonary embolus
7. Current tamoxifen use

Date of first enrolment
14/04/1992

Date of final enrolment
30/03/2011

Locations

Countries of recruitment
Australia

Belgium

England

Finland

Switzerland

United Kingdom

Study participating centre
Wolfson Institute of Preventive Medicine
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Sponsor information

Organisation
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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
Imperial Cancer Research Fund

Funder Name
Cancer Research Campaign

Funder Name
Cancer Research UK

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/09/2002		Yes	No
Results article	results	01/02/2003		Yes	No
Results article	results	21/04/2004		Yes	No
Results article	results	20/08/2006		Yes	No
Results article	results	21/02/2007		Yes	No
Results article	results	15/12/2009		Yes	No
Results article	results	04/05/2011		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	substudy results	01/01/2013		Yes	No
Results article	placebo arm results	08/10/2014		Yes	No
Results article	extended long-term follow-up results	01/01/2015		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	01/03/2017		Yes	No
Results article	results	10/08/2017		Yes	No
Results article	results	03/03/2021	04/03/2021	Yes	No