

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/04/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.ibis-trials.org/thetrials/ibistrials/ibis-1>

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-003091-38

ClinicalTrials.gov (NCT)

NCT00002644

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

Other cancers, other serious medical conditions or side effects

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

35 years

Upper age limit

70 years

Sex

Female

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

United Kingdom

England

Australia

Belgium

Finland

Switzerland

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

Imperial Cancer Research Fund

Funder Name

Cancer Research Campaign

Funder Name

Cancer Research UK

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes