

# Randomised double blind trial to evaluate prevention of breast cancer using tamoxifen in high risk women

<b>Submission date</b> 16/11/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
283A

# Study information

## Scientific Title

## Acronym

Tamoplac

## Study objectives

The hypothesis that oestrogen is an important promoter of carcinogenically induced mammary neoplasia opens up some attractive possibilities for the prevention of clinical breast cancers.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by the Royal Marsden Hospital Ethics Committee in October 1986.

## Study design

Randomised, controlled clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Women at high risk of developing breast cancer

## Interventions

20 mg/day oral tamoxifen versus placebo, treatment will continue for up to eight years.

## Intervention Type

Drug

## Phase

Not Specified

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

Tamoxifen

**Primary outcome measure**

Incidence of histologically confirmed invasive breast cancer

**Secondary outcome measures**

1. Death from breast cancer
2. Overall survival
3. Long-term changes in hormones, lipid profile and bone mineral density
4. Incidence of other disease, especially vascular

**Overall study start date**

01/10/1986

**Completion date**

01/10/2006

## **Eligibility**

**Key inclusion criteria**

1. Healthy women
2. Aged 30 to 70 years
3. Life expectancy of more than ten years
4. Psychologically and physically suitable for tamoxifen/placebo and long term follow-up
5. At increased risk of breast cancer by virtue of:
  - a. at least one first degree relative aged under 50 with breast cancer
  - b. one first degree relative with bilateral breast cancer
  - c. one first degree relative of any age plus another affected first or second degree relative
  - d. history of a high risk benign breast biopsy

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

2500

**Key exclusion criteria**

1. Clinical or screening evidence of breast cancer
2. Pregnant or lactating women
3. Pregnancy risk - unless a disclaimer was signed
4. Oral contraceptives within the previous three months
5. Previous history of non-invasive or invasive breast cancer

6. Previous history of other malignancy (except Basal Cell Carcinoma [BCC] or Carcinoma [CA] in situ of the cervix)

7. History of deep vein thrombosis or pulmonary embolism

**Date of first enrolment**

01/10/1986

**Date of final enrolment**

01/10/2006

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Parkside Oncology Clinic**

London

United Kingdom

SW19 5NB

## **Sponsor information**

**Organisation**

Royal Marsden Hospital (UK)

**Sponsor details**

Downs Road

Sutton

Surrey

England

United Kingdom

SM2 5PT

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.royalmarsden.nhs.uk/rmh>

**ROR**

<https://ror.org/034vb5t35>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

The Royal Marsden Hospital (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?
<a href="#">Results article</a>	Results publication:	11/07/1998		Yes	No