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

Submission date	Recruitment status	Prospectively registered
16/11/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
26/01/2007	Completed	[X] Results
Last Edited	Condition category	Individual participant data
08/05/2012	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Trevor Powles

Contact details

Parkside Oncology Clinic 49 Parkside Wimbledon London United Kingdom SW19 5NB

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?
Results article	Results publication:	11/07/1998		Yes	No