ISRCTN07027313 https://doi.org/10.1186/ISRCTN07027313

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

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