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Introduction of breast cancer prevention with tamoxifen for high risk premenopausal women in the UK (TAMoxifen Prevention study - TAM-P)

Submission date 25/10/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 26/10/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/10/2022	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-tamoxifen-prevent-breast-cancer-premenopausal-women-tam-prev

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10296

Study information

Scientific Title
Introduction of breast cancer prevention with tamoxifen for high risk premenopausal women in the UK (TAMoxifen Prevention study - TAM-P): a non-randomised study

Acronym
TAM-P

Study objectives
This study aims to determine uptake of tamoxifen for prevention in pre-menopausal women at increased risk of breast cancer. Women will be given a specially designed Decision Aid to assist them in deciding whether to join the study. Qualitative interviews will be conducted, both with a number of women who choose to join the study, and a number of women who decline to join the study. The Decision Aid will be re-designed based on the feedback given in these interviews. In addition, we aim to determine whether it is possible to predict who is most likely to benefit from preventive treatment with tamoxifen, by looking at oestrogen receptor expression and changes in mammographic breast density, lipid profiles, glucose, IGF-1, and body composition, before and after 12 months of tamoxifen treatment. Women will be given feedback about changes to the biomarkers associated with tamoxifen response, and will then be given the option to continue taking tamoxifen for a further four years, or stop at that point. Qualitative interviews will be conducted again at this point with a proportion of women who choose to continue, or discontinue taking tamoxifen. Economic analyses will also be carried out to determine the cost benefit to the NHS of prescribing tamoxifen for prevention in pre-menopausal women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Greater Manchester West, First MREC approval date 17/02/2011, ref: 11/H1014/14

Study design
Non-randomised; Interventional and Observational; Design type: Prevention, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

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

Interventions
Tamoxifen will be offered to pre-menopausal women at increased risk of breast cancer who attend the Family History Clinic and University Hospital of South Manchester

The intervention used in this study is tamoxifen 20mg to be taken once per day orally, initially for 12 months, with an option to continue for a further 48 months.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Uptake: Recruitment is over an 18-month period so will be assessed at the end of the 18 months

Secondary outcome measures
1. Reduction in breast density measured at 12-30 months
2. Oestrogen receptor (ESR) status and CYP2D6 status, measured from DNA collected from a blood tested at baseline
3. Changes in biomarkers - IGF-1, insulin, glucose and lipids measured from blood samples collected at baseline and after 12 months of tamoxifen use (in addition lipids will be assessed after 2 months of tamoxifen use)
4. Body weight and composition, measured at baseline, and after 2 and 12 months of tamoxifen. This will be measured using the Tanita 180, Tanita UK Ltd scales. Waist and hip measurements will be done using standard tape measures, at baseline, and after 2 and 12 months of tamoxifen
5. Cost-effectiveness - symptom and healthcare resource use diary used to assist in economic evaulation

Overall study start date
02/05/2011

Completion date
30/11/2013

Eligibility

Key inclusion criteria
1. Pre-menopausal
2. Attends the Family History Clinic at the Nightingale & Genesis Prevention Centre
3. At moderate or high risk of breast cancer

4. Normal mammogram
5. Willing to use a non-hormonal form of contraception (mirena coil is permitted)
6. Upper Age Limit 46 years ; Lower Age Limit 33 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment
136

Key exclusion criteria
1. Use of coumarin type anticoagulants
2. Use of droperidol
3. Use of Bupropion
4. Diabetes (type I or II)
5. Use of hormonal contraceptives within 3 monhts of joining the study (mirena coil is permitted)
6. Pregnancy and breastfeeding
7. Prophylactic mastectomy or plans to have this procedure
8. Personal or family history of thromboembolism
9. Previous cancer in the last five years (except basal cell carcinoma or in situ cancer of the cervix)
10. Symptomatic gynaecological problems requiring medication

Date of first enrolment
02/05/2011

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshaw Hospital
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester (UK)

Sponsor details
Wythenshawe Hospital
Southmoor Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
The Genesis Breast Cancer Prevention Appeal (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			25/10/2022	No	Yes