

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

<b>Submission date</b> 25/10/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

### Contact name

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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

**Key secondary outcome(s)**

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 evaluation

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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 months 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**

United Kingdom

England

**Study participating centre**

**Wythenshaw Hospital**

Manchester

United Kingdom

M23 9LT

## **Sponsor information**

**Organisation**

University Hospital of South Manchester (UK)

**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

**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?
<a href="#">Plain English results</a>			25/10/2022	No	Yes