

Digital breast tomosynthesis in screening younger higher risk women

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|--|---|---|
| Submission date 03/04/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/04/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 23/04/2021 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-study-comparing-digital-breast-tomosynthesis-standard-mammogram-screening-younger-high-risk-women>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16312

Study information

Scientific Title

A randomised trial of screening with digital breast tomosynthesis plus conventional digital 2D mammography versus 2D mammography alone in women aged 40 to 49 at increased risk of breast cancer

Acronym

FHtomo

Study objectives

Mammographic screening is performed to detect breast cancer. Tomosynthesis is a new way of performing mammography that uses x-rays and a computer to generate three-dimensional (3D) images of the breast. The purpose of this study is to compare the accuracy of tomosynthesis and standard 2D mammography in the diagnosis of breast abnormalities, and in particular whether tomosynthesis can reduce the number of false alarms which lead to further tests.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/NW/0053; First MREC approval date 19/02/2014

Study design

Randomised; Interventional; Design type: Screening

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format. Please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Cancer; Subtopic: Breast Cancer; Disease: Breast

Interventions

Participants who have not had a screening mammogram before will have a standard 2D mammogram and DBT.

Women who have undergone screening mammography prior to entering the trial will be randomised using a web-based randomisation service to undergo either standard 2D mammography only followed a year later by 2D mammography and DBT, or the reverse (i.e. 2D mammography and DBT followed a year later by 2D mammography only). Participants will return to the standard screening schedule in the Family History Clinic following the trial.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Recall to assessment rate; Timepoint(s): At screening

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2014

Completion date

30/09/2016

Eligibility**Key inclusion criteria**

Women aged 40 to 49 years inclusive with an increased risk of breast cancer by virtue of their family history and who have been referred for screening by a family history or genetics service. (Note some women will be aged 50 when they have their second screen within the study)
Target Gender: Female; Upper Age Limit 50 years ; Lower Age Limit 40 years

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Planned Sample Size: 2904; UK Sample Size: 2904

Total final enrolment

1227

Key exclusion criteria

1. Inability to give informed consent, including inability to understand the nature and purpose of the study
2. Breast implants
3. Pregnancy
4. Previous breast cancer

Date of first enrolment

01/04/2014

Date of final enrolment

30/09/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Genesis Prevention Centre

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester (UK)

Sponsor details

Wythenshawe Hospital, Southmoor Road

Wythenshawe

Manchester

England

United Kingdom

M23 9LT

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Charity

Funder Name

Genesis Breast Cancer Prevention Appeal Ltd (UK); Grant Codes: GA13-007

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? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| Plain English results | | | 23/04/2021 | No | Yes |
| Results article | | 01/09/2017 | 23/04/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |