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Digital breast tomosynthesis in screening younger higher risk women

Submission date	Recruitment status	[_] Prospectively registered
03/04/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/04/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2021	Cancer	

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

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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
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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