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TOMMY trial: A comparison of TOMosynthesis with digital MammographY in the UK NHS Breast Screening Programme

Submission date	Recruitment status	[_] Prospectively registered
06/05/2011	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
06/05/2011	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
26/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-standard-mammograms-with-new-type-digital-mammogram-screen-for-breast-cancer-tommy-trial

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9464

Study information

Scientific Title
A non-randomised interventional study comparing TOMosynthesis with digital MammographY in the UK NHS Breast Screening Programme

Acronym
TOMMY trial

Study objectives
The trial will compare the accuracy of digital breast tomosynthesis (DBT) with standard digital full field mammography (FFDM) in the diagnosis of breast cancer.

A limitation of standard mammography is that overlapping dense fibroglandular tissue in normal breast tissue can decrease the visibility of malignant abnormalities, or mimic abnormalities. DBT is a newly developed three dimensional (3D) imaging technique that has the potential to improve the accuracy of mammography by reducing interference from tissue overlap and facilitating differentiation between malignant and non malignant features.

The aim of the trial is to assess whether DBT could improve upon digital mammography as a screening tool, particularly in certain groups of women e.g. those with a family history of breast cancer, or women with dense breasts. The diagnostic accuracy of DBT, FFDM and DBT+FFDM will be evaluated in an independent retrospective reading study in and compared to the final clinical outcome for each case.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee; First MREC approval date 27/05/2010, 10/MRE00/39

Primary study design
Interventional

Study design
Non-randomised; Interventional; Design type: Diagnosis

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
Participants will be recruited over a 15-18 month period from six UK Breast Screening Centres. This should provide sufficient cancer cases to compare the sensitivity and specificity of the three imaging modalities.

Participants in the trial will have a standard two-view (MLO and CC) digital mammography examination of each breast and a two-view (MLO and CC) digital breast tomosynthesis examination of each breast. The digital mammogram and tomosythesis imaging will be acquired during the same breast compression

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
1. Cancer detection rate (early stage cancers (<15mm)/subtle lesions/cancers in women with dense breasts); Timepoint(s): At end of retrospective reading study
2. Recall rate; Timepoint(s): At end of retrospective reading study

Key secondary outcome(s)
Visibility of multifocal lesions and microcalcification detection

Completion date
29/06/2012

Eligibility

Key inclusion criteria
1. Women (aged 47-73) recalled to an assessment clinic following abnormal screening mammography
2. Women (aged 40-49) with a family history of breast cancer attending annual screening mammography; Target Gender: Female; Upper Age Limit 73 years ; Lower Age Limit 40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
8869

Key exclusion criteria
1. Women unable to give informed consent, including anyone unable to understand the nature and purpose of the study
2. Women with breast implants
3. Women who are pregnant

Date of first enrolment
01/02/2011

Date of final enrolment

29/06/2012

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Aberdeen Biomedical Imaging Centre
Aberdeen
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Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR)-HTA (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?
Results article	results	01/01/2015		Yes	No
Results article	results	01/05/2015		Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			26/10/2022	No	Yes