

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

Submission date 06/05/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Study design

Non-randomised; Interventional; Design type: Diagnosis

Primary study design

Interventional

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 tomosynthesis 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

United Kingdom

AB25 2ZD

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes