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CONTEST Study - Accuracy of contrast enhanced breast tomosynthesis: A comparison with digital mammography and breast MRI

Submission date 31/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 12/02/2018	**Overall study status** Completed	
Last Edited 08/11/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Breast cancer is the most common type of cancer in the UK. Some women, particularly younger women, have dense breast tissue, which makes it harder to spot cancers or areas of concern on a standard breast x-ray (mammogram). A new kind of x-ray called Contrast Enhanced Digital Breast Tomosynthesis (CE-DBT) may be particularly useful in these patients as it can highlight areas of concern even if the breasts are dense.
The aim of the study is to find out whether CE-DBT is better than a standard mammogram, and is as good as breast magnetic resonance imaging (MRI) to show tumour size.

Who can participate?
Women between the ages of 18-70 years old who have a high suspicion of breast cancer that can be operated on.

What does the study involve?
Participants receive a standard mammogram, and the new procedure CE-DBT. For this, participants have a special dye called contrast medium injected into the veins before the x-ray is taken. Some participants also have an MRI scan and all receive an ultrasound scan. If there are any areas of concern in the breast the participants may have a sample of cells taken by a needle biopsy.
Everybody completes a short questionnaire after the CE-DBT procedure and MRI scan to provide information about how they felt during each procedure.

What are the possible benefits and risks of participating?
Although it is not known, CE-DBT may provide better information than the standard tests potentially resulting in receiving the right diagnosis more quickly. There is also a chance that it will be easier to work out the most suitable treatment for a patient and increase certainty that no areas of concern have been missed if a participant's results show no serious breast problem.
The injection needed for this test is generally very safe. However, with every injection of the dye, there is a very slight risk of a reaction. Some participants may develop a rash, and a few people may get a mild asthma attack. More serious reactions are very unusual.

The dye used for the test can affect the kidneys (less than 1 in 100 people). The test will not be offered if there are any risk factors or known kidney problems.
All x-rays involve radiation. The amount of radiation from a standard mammogram is small. It is similar to the amount of radiation received naturally from the environment over a period of a few months. The radiation dose from CE-DBT is higher than that of a standard mammogram, but still well within accepted safety guidelines.

Where is the study run from?
Ninewells Hospital Dundee (UK)

When is the study starting and how long is it expected to run for?
June 2017 to July 2023

Who is funding the study?
Chief Scientist Office (Scotland)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
237233

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2017ON01, IRAS 237233

Study information

Scientific Title
CONTEST study: CONTrast Enhanced breaSt Tomosynthesis (CONTEST) in patients suspected of having breast cancer: a prospective comparison with digital mammography and breast MRI

Acronym
CONTEST

Study objectives
The aim of this study is to evaluate the performance of contrast-enhanced digital breast tomosynthesis (CE-DBT) in the identification and local staging of symptomatic breast cancer. We hypothesise that the diagnostic performance of CE-DBT will be significantly better than that of digital mammography (DM) and that it will not significantly differ from breast MRI in local staging and evaluation of local extent of breast cancer. The primary objective is to determine the incremental increase in sensitivity of CE-DBT over DM alone in women with symptoms/signs suspicious for breast cancer, the latter currently being standard of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service (REC2), 09/01/2018, ref: 17/NS/0123

Study design
Prospective single-centre paired comparison study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Cancer

Interventions
All participants receive the equivalent of standard care, a Digital Mammogram (DM) and the experimental procedure which is the Contrast Enhanced Digital Breast Tomosythesis (CE-DBT). Needle biopsy is carried out according to standard clinical practice if there are any areas of concern. All recruits with biopsy-proven breast cancer also undergo breast MRI but in a proportion this will be a study-specific procedure, and participants complete a short questionnaire after the CE-DBT and MRI to inform how they felt during the procedures.

Intervention Type
Procedure/Surgery

Primary outcome measure
Sensitivity of CE-DBT compared with DM using surgical pathology as the gold standard.

Secondary outcome measures
1. Correlation of tumour size measurements with CE-DBT compared to MRI, using surgical pathology as the gold standard
2. Identification of multifocality with CE-DBT compared to MRI, using surgical pathology as the gold standard
3. Patient perspectives on the CE-DBT procedure is measured using a questionnaire after the procedure
4. Patient perspectives on the MRI scan is measured using a questionnaire after the procedure

Overall study start date
28/06/2017

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age 18 to 70 years inclusive
2. Female
3. Able to give informed consent

4. Clinical examination findings suspicious or typical of operable breast cancer (E4/5)
AND/OR
5. Ultrasound findings suspicious or typical of malignancy (U4/5)
6. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Female

Target number of participants
200

Total final enrolment
87

Key exclusion criteria
1. History of prior iodinated contrast reaction
2. Iodine allergy
3. Severe asthma
4. Known renal impairment, strong risk factors for renal disease
5. Previous breast cancer surgery or implants
6. Current pregnancy, lactation
7. Inflammatory or clinically obvious locally advanced (inoperable) primary breast cancer who are likely to receive neoadjuvant chemotherapy (in these patients, imaging/pathological correlation will not be possible)
8. Contraindication to MRI
9. Obvious severe comorbidities precluding operative treatment
10. Otherwise deemed to be unsuitable by the clinical team

Date of first enrolment
01/05/2018

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Ninewells Hospital
Ninewells Avenue
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Sponsor information

Organisation
University of Dundee and NHS Tayside

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Sponsor type
University/education

Website
http://www.ahspartnership.org.uk/tasc

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (Scotland)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The data is held by the sponsor. After 5 years of publication, data can be requested from the chief investigator or sponsor. Sharing of data will be subject to a Material Transfer Agreement being in place.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	31/05/2021	05/09/2022	No	No
HRA research summary			28/06/2023	No	No