

Multidetector computed tomography to improve surgical outcomes in breast cancer

Submission date 13/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/03/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/trial-looking-at-ct-scans-before-surgery-breast-cancer>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 2

Study information

Scientific Title

Multidetector Computed Tomography to Improve Surgical Outcomes in Breast Cancer (MISOBC): a randomised controlled trial

Acronym

MISO-BC

Study objectives

This study is a prospective randomised open blinded end-point (PROBE) study comparing routine and CT-enhanced diagnostic and surgical care in patients presenting with primary breast cancer in whom axillary surgery is planned.

Currently SLNB has a 25% re-operation rate (ALNB) if malignant lymph nodes are found in the axilla at the initial operation in our hospital.

The study is designed to detect a reduction in re-operation rate to 10% . This is the primary scientific aim of the study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Newcastle and North Tyneside Research Ethics Committee (REC) 2, 14/09/2010, ref: 10 /H0907/42

Study design

Randomised controlled trial using a PROBE design (prospective randomised open blinded end-point)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Breast cancer

Interventions

When patients present with breast symptoms they are usually referred by their general practitioners for assessment in a one-stop breast clinic. At the clinic, they will undergo clinical assessment by a breast surgeon, and ultrasound and mammography (depending on the age of the patient), as well as needle sampling of the breast lump (usually either Fine Needle Aspiration Cytology or Core Biopsy).

When there is a positive diagnosis of a breast cancer made, the patients are informed at a second outpatient appointment by a consultant breast surgeon. After they have received their diagnosis, the surgeon will discuss the MISO BC trial with them and provide them with a patient information leaflet. The surgeon will ask the patient whether they would be willing to be contacted in the near future about possible participation in the trial. Within two to four days, the patients who have agreed contacted will be phoned by the Site Trial Coordinator (STC), who will discuss the trial with them. If the patient wishes to enter the trial, the STC will take verbal consent, which will be recorded in writing in the patient notes. The STC will then randomise the patient and convey the result to them. If they are randomised to the group having the CT scan, an appointment within a week will be provided for the patient to attend to have the scan. Written consent for the trial will be obtained by the Trial Nurse at the time of the CT scan.

For those patients randomised to the group not having a CT scan, the Site Trial Coordinator will confirm with the patient when their next hospital attendance will be and arrange to meet them. Written consent will be obtained for entry into the trial by the Site Trial coordinator at the next hospital attendance which will usually be for preassessment for surgery.

Patients from both groups will have undergone a routine axillary ultrasound examination with or without core biopsy at the time of their initial assessment in the one stop breast clinic. The non CT axilla group will have their axillary surgery as planned.

Patients who are randomised to have a CT scan will have their scan performed through the ipsilateral axilla (same as the side of the cancer) using the 64 slice Aquilion scanner (Toshiba Medical) at the University Hospital of North Durham. CT and other diagnostic test procedures will be conducted and recorded in a blinded fashion. The findings, together with the results of axillary ultrasound, will be discussed at the Breast MDT and the appropriate axillary surgery (either SLNB or ALND) decided upon.

Test results will then be correlated with histopathological results obtained from the axillary surgery (the test reference standard) in order to determine the sensitivity and specificity of the CT examination. Histopathological determination will be conducted by a pathologist blinded to test findings. Thus the test performance of ultrasound (+/- core biopsy) and CT alone and in combination will be estimated.

After the axillary surgery, the status of the nodal disease together with any further required surgery or management of complications will be recorded within trial. Approximately two weeks after the final episode of surgery, the patients will be telephoned by the Site Trial Coordinator and interviewed about their experiences. Additional data required for the trial will be extracted from the medical notes for each patient that consents to the trial.

The trial period will extend from the time of verbal consent to two weeks after the last surgical procedure. The subjects will be contacted by the Site Trial Coordinator who will then go through the Patient Experience Survey with them. This will represent the end of the patients' participation in the trial. As a guide for most patients, the total duration of the trial period will be between 4-8 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in the rate of re-operation on the axilla when comparing CT-informed and routine care.

Secondary outcome measures

1. Patient satisfaction (as evidenced by patient satisfaction questionnaires) at 2 weeks post surgery
2. The sensitivity, specificity, and positive and negative predictive values of ultrasound of the axilla, ultrasound with needle sampling and mulidetector CT
3. Economic analysis
4. Rates of common post surgical complications in both groups including wound infections, serous axillary collections, and lymphoedema

Overall study start date

01/11/2010

Completion date

01/05/2013

Eligibility**Key inclusion criteria**

1. Male or female, aged 18 years or over
2. Have undergone ultrasound scanning and/ or mammography for their current breast cancer diagnosis
3. Have pathologically documented primary invasive breast carcinoma
4. Be suitable for axillary surgery
5. Be able to provide written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Are medically unstable as judged by the Chief Investigator or Trial Nurse
2. Are known to have had an allergic reaction associated with previous administration of iodinated contrast agent or have a severe allergic diathesis
3. Require renal dialysis
4. Have had previous surgery or radiotherapy for cancer to the ipsilateral (same side) axilla
5. Pregnant patients

Date of first enrolment

01/11/2010

Date of final enrolment

01/05/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University Hospital North Durham

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Sponsor information**Organisation**

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00vwfb160>

Funder(s)

Funder type

Government

Funder Name

National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)
Programme (ref: PB-PG-0609-18085)

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?
Results article	results	01/04/2017		Yes	No