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Multidetector computed tomography to improve surgical outcomes in breast cancer

Submission date 13/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/11/2010	**Overall study status** Completed	
Last Edited 27/03/2018	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/trial-looking-at-ct-scans-before-surgery-breast-cancer

Contact information

Type(s)
Scientific

Contact name
Dr Julie Cox

Contact details
Department of Radiology
University Hospital North Durham
Durham
United Kingdom
DH1 5TW
+44 (0)191 333 2491
julie.cox@cddft.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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

United Kingdom

England

Study participating centre
University Hospital North Durham
Durham
United Kingdom
DH1 5TW

Sponsor information

Organisation
Darlington Memorial Hospital (UK)

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

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