

Magnetic versus standard technique for sentinel node biopsy in breast cancer

Submission date 13/11/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/12/2014	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer refers to a condition where tumours develop in the tissue of the breast. In the UK, 49,500 women are diagnosed with breast cancer every year. Sentinel lymph nodes are those lymph nodes where a cancer is most likely to spread to first. Sentinel Lymph Node Biopsy (SLNB) is a procedure that helps determine the extent of the cancer, or how advanced it is. The standard surgical technique for SLNB is the 'dual' technique. It consists of a radioisotope injection and an injection of blue dye into the breast. Any sentinel nodes are then found using a gamma probe device. Worldwide, access to SLNB is limited by the lack of availability of the radioisotopes. Only about 60% of patients in developed countries have access to this procedure. In China only 5% of patients have access and in the remaining countries it is more or less unavailable. Patients without access to SLNB have to undergo a bigger operation which carries a 20% risk of permanent swelling of the arm (lymphoedema). The aim of this study is to test a new magnetic technique for SLNB in breast cancer patients compared with the standard dual technique. The new technique consists of an injection of a magnetic tracer into the breast. A hand-held device (a magnetometer) is then used to find any sentinel nodes during the operation. The study will compare the performance of both techniques, any illness caused by either technique, and any progression of the breast cancer disease afterwards.

Who can participate?

Patients diagnosed with breast cancer and undergoing a SLNB.

What does the study involve?

Patients are randomly allocated into one of two groups. Those in group 1 are treated using the magnetic technique for SLNB. Those in group 2 are treated using the standard technique for SLNB. The number of sentinel lymph nodes found is recorded for both the standard technique and the magnetic technique.

What are the possible benefits and risks of participating?

Research is an important part of improving the quality of medical care and developing new and innovative treatments. This research will have no direct benefit for the research participants but by taking part in this study we hope to improve other patients' treatment in the near future. Skin discolouration has been observed in previous studies but it tends to resolve on its own. The

magnetic tracer can cause an artefact on subsequent breast MR imaging. There is a chance of developing adverse reactions to the magnetic tracer. Hypersensitivity reactions (rash, itching, dizziness, light-headedness) have been observed in less than 1% of patients with similar tracers (or MRI contrast agents). In this study, the chance of developing adverse reactions to the magnetic tracer are very low as a lower dose is used. It is injected locally into the skin and most of the tracer is surgically removed when the tumour and lymph nodes are removed.

Where is the study run from?

Guy's & St Thomas' Foundation NHS Trust (UK).

When is the study starting and how long is it expected to run for?

January 2015 to January 2020.

Who is funding the study?

J P Moulton Charitable Foundation (UK).

Who is the main contact?

Mr Michael Douek

Contact information

Type(s)

Scientific

Contact name

Mr Michael Douek

Contact details

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

MAGnetic versus STAndard technique for sentinel node biopsy in breast cancer: a Randomised controlled trial

Acronym

MAGSTAR

Study objectives

The standard Sentinel Lymph Node Biopsy (SLNB) technique (blue dye and radioisotope) used in breast cancer patients has several drawbacks. The use of radioisotope exposes patients and healthcare workers to radiation and is heavily controlled by legislation (both on the specific training for operators and subsequent disposal of surgical waste).

The MAGSTAR trial compares a new technique for SLNB versus the standard technique. This new technique uses two devices: an injection of a magnetic tracer (Sienna+, Endomagnetics Ltd, UK) and the use of a hand-held device (a magnetometer, SentiMag, Endomagnetics Ltd, UK) to detect the sentinel node(s) intraoperatively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Fulham Ethics, 05/03/2015, ref: 15/LO/0289

Study design

Phase III randomised controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Breast cancer

Interventions

SLNB with the standard combined technique (blue dye and radioisotope) or the new technique (magnetic tracer and hand-held magnetometer). Interventions are the injection of the radioisotope, blue dye and magnetic tracer. Furthermore, the detection and localization of the sentinel lymph node with gammaprobe (standard arm) or the hand-held magnetometer (magnetic arm).

Intervention Type

Other

Primary outcome(s)

1. Overall SLNB identification rate (proportion of successful SLNBs) with either the standard or the new technique
2. SLNB identification rate within the cohort of patients with involved nodes

Key secondary outcome(s)

1. Morbidity from SLNB (including staining and lymphoedema rate)
2. Locoregional recurrence
3. Cost effectiveness (health economics)
4. Patient-reported outcome measures (PROMS) with both techniques

Completion date

01/01/2020

Reason abandoned (if study stopped)

Supply issues of the device and emerging data from other trials using the blue dye

Eligibility

Key inclusion criteria

Patients with breast cancer scheduled for SLNB and who are clinically and radiologically node negative

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Known intolerance/hypersensitivity to iron or dextran compounds
2. Patients who decline to receive radioisotope for SLNB
3. Patients with a pacemaker or other implantable devices in the chest wall

Date of first enrolment

01/01/2015

Date of final enrolment

01/01/2020

Locations

Countries of recruitment

United Kingdom

England

Netherlands

Study participating centre

Guy's & St Thomas' Foundation NHS Trust

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust

ROR

<https://ror.org/00j161312>

Organisation

King's College London

Funder(s)

Funder type

Charity

Funder Name

The J P Moulton Charitable Foundation (UK)

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?
HRA research summary			28/06/2023	No	No