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# Magnetic versus standard technique for sentinel node biopsy in breast cancer

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| **Submission date**<br>13/11/2014 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>15/12/2014 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>09/04/2021 | **Condition category**<br>Cancer | |

## 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. Sentinal 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
Guy's & St Thomas' Foundation NHS Trust
Research Oncology
3rd Floor Bermondsey Wing
Great Maze Pond
London
United Kingdom
SE1 9RT

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Diagnostic

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

## 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 measure
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

### Secondary outcome measures
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

### Overall study start date
01/01/2015

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
924

### 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**
England

Netherlands

United Kingdom

**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

**Sponsor details**
c/o Dr Kate Blake
R&D Department
16th Floor, Tower Wing
Great Maze Pond
London
England
United Kingdom
SE1 9RT

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.guysandstthomas.nhs.uk/Home.aspx

**ROR**
https://ror.org/00j161312

**Organisation**

King's College London

### Sponsor details
c/o Keith Brennan
Room 1.8
Hodgkin Building
Guy's Campus
King's College London
London
England
United Kingdom
SE1 1UL

### Sponsor type
University/education

## Funder(s)

### Funder type
Charity

### Funder Name
The J P Moulton Charitable Foundation (UK)

## 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |