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# SentiMAG multicentre trial

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| **Submission date**<br>29/11/2012 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/02/2013 | **Overall study status**<br>Completed | |
| **Last Edited**<br>11/12/2013 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-new-way-find-sentinel-lymph-nodes-breast-cancer-sentimag

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
11/LO/1972

# Study information

### Scientific Title
Sentinel node biopsy using MAGnetic nanoparticles: A prospective multicentre phase II non-randomised clinical trial to compare sentinel node biopsy using magnetic nanoparticles vs. standard technique

### Acronym
SentiMAG

### Study objectives
The standard Sentinel Lymph Node Biopsy (SLNB) technique (patent blue dye and radioisotope; or radioisotope alone) used in breast cancer patients has several drawbacks. The use of radioisotope exposes patients and healthcare workers to radiation, is heavily controlled by legislation (both on the specific training for operators and subsequent disposal of surgical waste), and provides poor pre-operative imaging.

The SentiMAG multicentre trial evaluates a new technique for SLNB against the standard technique. This new technique uses two devices: a subcutaneous injection of a magnetic tracer (Sienna+) into the breast and the use of a hand-held device (a magnetometer, SentiMag) to detect the sentinel node(s) intraoperatively.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee London - London Bridge ,06th February 2012, ref: 11/LO/1972

### Study design
Prospective multicentre phase II non-randomised clinical trial

### Primary study design
Interventional

### Secondary study design
Non 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 patient information sheet

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

### Interventions
SLNB with the standard (patent blue dye and radioisotope; or radioisotope alone) 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 and the hand-held magnetometer.

Pre- and post contrast MRI scan of the axilla.

Details of secondary sponsor:
Guy's and St. Thomas' NHS Foundation Trust
Westminster Bridge Rd
London Borough of Lambeth
London SE1 7EH
UK

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Radioisotope, patent blue dye

### Primary outcome measure
SLNB technique: The proportion of sentinel nodes detected (detection rate) with either the standard (patent blue dye and radioisotope; or radioisotope alone) or the new technique (magnetic tracer and hand-held magnetometer).

MRI sub protocol: Accuracy of MRI for the localisation of SLNs.

### Secondary outcome measures
Morbidity from SLNB including lymphoedema, numbness, seroma, cutaneous staining, shoulder stiffness, chronic pain and locoregional recurrence.

### Overall study start date
01/02/2012

### Completion date
01/02/2017

## Eligibility

### Key inclusion criteria
1. Patients with breast cancer scheduled for SLNB and who are clinically and radiologically (pre-operative ultrasound normal or indeterminate/abnormal and benign FNA or core biopsy) node negative
2. Patients available for follow-up for at least 12 months

### Participant type(s)

Patient

**Age group**
Adult

**Sex**
Female

**Target number of participants**
160

**Key exclusion criteria**
1. Intolerance / hypersensitivity to iron or dextran compounds or Sienna +
2. Patients who cannot / do not receive radioisotope for SLNB
3. Patients with an iron overload disease
4. Patients with pacemakers or other implantable devices in the chest-wall
5. Intolerance / hypersensitivity to patent blue dye in centres where this is used routinely

**Date of first enrolment**
01/02/2012

**Date of final enrolment**
01/02/2017

# Locations

**Countries of recruitment**
England

Netherlands

United Kingdom

**Study participating centre**
**King's College London**
London
United Kingdom
SE1 9RT

# Sponsor information

**Organisation**
King's College London (UK)

**Sponsor details**

Room 1.8 Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 1UL

### Sponsor type
University/education

### Website
http://www.kcl.ac.uk

### ROR
https://ror.org/0220mzb33

## Funder(s)

### Funder type
University/education

### Funder Name
King's College London (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? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2014 | | Yes | No |