

# SentiMAG multicentre trial

<b>Submission date</b> 29/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/12/2013	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Diagnostic

## **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(s)**

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.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

Netherlands

**Study participating centre**

**King's College London**

London

United Kingdom

SE1 9RT

## Sponsor information

**Organisation**

King's College London (UK)

**ROR**

<https://ror.org/0220mzb33>

## Funder(s)

**Funder type**

University/education

**Funder Name**

King's College London (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?
<a href="#">Results article</a>	results	01/04/2014		Yes	No