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SentiMAG multicentre trial

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