

SentiMAG multicentre trial

Submission date 29/11/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/02/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/12/2013	Condition category Cancer	☐ 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

Mr Michael Douek

Contact details

King's College London
Dept of Research Oncology
3rd Floor Bermondsey Wing
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT
janet.mac_sweeney@kcl.ac.uk

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

Primary study design

Interventional

Study design

Prospective multicentre phase II non-randomised clinical trial

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?
Results article	results	01/04/2014		Yes	No