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Sentinel Node Biopsy using Magnetic Nanoparticles for melanoma

Submission date	Recruitment status	[ ] Prospectively registered
22/08/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/08/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/08/2013	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-magnetic-tracer-find-most-likely-lymph-nodes-melanoma-spread-melamag

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14011

Study information

Scientific Title
Node Biopsy using Magnetic Nanoparticles: A prospective multicentre feasibility non-randomised clinical trial for melanoma

Acronym

MELAMAG Trial

Study objectives
The standard Sentinel Lymph Node Biopsy (SLNB) technique (patent blue dye and radioisotope) used in melanoma 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 MELAMAG trial evaluates a new technique for SLNB against the standard technique. This new technique uses 2 devices: a intradermal injection of a magnetic tracer (Sienna+) 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)
12/EE/0522; First MREC approval date 07/02/2013

Study design
Non-randomised; Interventional; Design type: Diagnosis

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Melanoma; Disease: Melanoma

Interventions
1. Ex-vivo MRI: In centres that participate in the ex-vivo MRI sub protocol an ex-vivo MRI scan from the sentinel lymph nodes is performed.
2. Injection magnetic tracer: The magnetic tracer is injected intradermally when the patient is anaesthetized.
3. Pre-operative MRI: In centres that participate in the MRI sub protocol a pre-operative MRI scan is performed after injection of magnetic tracer.
4. Sentinel Lymph Node Biopsy: The sentinel lymph node biopsy procedure is performed with the gamma probe as per normal protocol, in addition to that the hand-held magnetometer is used first to localize sentinel lymph nodes.
Follow Up Length: 12 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Phase II

Primary outcome(s)

Detection rate with either the standard (blue dye and isotope) or the new technique (magnetic)
Timepoint(s): The proportion of sentinel nodes detected (detection rate) with either the standard or the new magnetic technique

Key secondary outcome(s))
1. Evaluate surgeon's experience; Timepoint(s): Also to evaluate the surgeon's experience with the SentiMag technique and estimate the number of ope
2. Morbidity from SLNB; Timepoint(s): Morbidity from SLNB including lymphoedema, numbness, seroma, infection, cutaneous staining, chronic
3. MRI Scan; Timepoint(s): To evaluate the accuracy of MRI for the localisation of SLNs

Completion date
04/03/2018

Eligibility

Key inclusion criteria
1. Patients with primary cutaneous melanoma scheduled for SLNB and who are clinically AJCC stage IB-IIC.
2. Patients available for follow-up for at least 12 months
Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Intolerance / hypersensitivity to iron or dextran compounds
2. Patients who cannot / do not receive radioisotope for SLNB
3. Patients with pacemakers or other implantable devices in the chest wall
4. Patients who had previous surgery to the likely draining lymph node fields
5. Patients with surgical scars between the primary biopsy site the draining lymph node field that may alter the lymphatic drainage pattern
6. Patients with pre-existing lymphedema at the primary biopsy site, either primary or secondary

Date of first enrolment
16/04/2013

Date of final enrolment

04/03/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Technology Strategy Board (UK)

Alternative Name(s)
TSB

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

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?
HRA research summary			28/06/2023	No	No