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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## 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 below to request a patient information sheet

## 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 measure
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

### Secondary outcome measures
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

### Overall study start date
16/04/2013

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex

Both

### Target number of participants
Planned Sample Size: 160; UK Sample Size: 130; Description: 30 Patients will be recruited in The Netherlands.First analysis will be performed as per protocol after recruitment of 50 patients

### 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
England

United Kingdom

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

## Sponsor information

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

### Sponsor details
Hodgkin Building
New Hunts House
Guy's Campus King's College London
London
England

United Kingdom
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**Sponsor type**
University/education

**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

**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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |