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

Contact name

Mr Bauke Anninga

Contact details

Great Maze Pond London United Kingdom SE1 9RT bauke.anninga@gstt.nhs.uk

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 nonrandomised 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 SE1 1UL

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