MelaMag Multicentre Trial

Gepubliceerd: 16-05-2013 Laatst bijgewerkt: 18-08-2022

The new technique for sentinel node biopsy is non-inferior to the standard technique used.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23789

Bron
NTR

Aandoening

sentinel node biopsy
Sienna+
SentiMag
MRI

Ondersteuning

Primaire sponsor: King's College London, Guy's & St Thomas' NHS Foundation Trust
Overige ondersteuning: Technology Strategy Board CR&D - Biomedical Catalyst: Feasibility Award
For Medisch Spectrum Twente, the University of Twente funds the MRI study and the Sienna+ injected.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint: 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).

Toelichting onderzoek

Achtergrond van het onderzoek

The MelaMag Mutlicenter Trial is a phase II paired equivalence trial. It will initially involve 6 centres and will be coordinated from King's College London (Guy's Hospital) by the Chief Investigator. The trial aimed to recruit 160 patients. Centres will be invited to recruit 30 patients and the trial will be closed once the target number of 160 complete patient datasets has been reached.

Patients will receive a radioisotope injection and a subcutaneous injection of Sienna+ close to the tumour. This may be given between up to thirty minutes before surgery. In centres that also participate in the MRI subprotocol, patients will undergo a pre-operative MRI before and after the injection of Sienna+. Ath the Medisch Spectrum Twente pre-operative MRI scans will be performed depending on the availability of the MRI scanning slots.

Intra-operatively, patients will receive an intradermal injection of patent blue (Guerbet, Parijs). All sentinel nodes detected intra-operatively using either the gamma probe or SentiMag; or demonstrating blue or black staining will be excised. In the lead centre (and any other sites participating in the MRI subprotocol), ex-vivo MRI scans of the excised nodes will be undertaken using a high-resolution MRI scanner. In the Medisch Spectrum Twente an ex-vivo MRI scan of the excised nodes is not possible. At the University of Twente in Enschede the amount of iron in each excised node will be measured using a quantitative magnetometer.

All lymph nodes will be assessed histologically and the nodal status will be related back to the SLNB detection rate with each technique.

Patients will be followed post-operatively (7-14 days after surgery) to assess if staining occurs or for any other adverse event. If staining is present, photographs will be taken. Further follow-up is at 3 months and at 1 year. Patients will be followed up for a total of 5 years, in accordance with current local policies.

Doel van het onderzoek

The new technique for sentinel node biopsy is non-inferior to the standard technique used.

Onderzoeksopzet

The study in the Medisch Spectrum Twente will include 30 patients in the period from 01-06-2013 until 01-12-2014

Onderzoeksproduct en/of interventie

The Medisch Spectrum Twente will participate in the MRI subprotocol. As part of the MRI subprotocol, patients will undergo an MRI scan prior to the scheduled operation. The scan will take roughly 60 minutes and involves lying down in a tubular scanner. Once positioned in the scanner, an initial scan will be undertaken. Following the initial scan, a subcutaneous injection of 0,5-1mL Sienna+ near the tumour is given and a second scan is performed. The scan may need to be repeated at 2 hours or at 24 hours after the initial scan but further injections will not be required.

The operation will be performed as already planned by the surgeon. In addition to the normal patent blue dye and radioactive injection, an additional injection of Sienna+ is administered close to the tumour (an additional Sienna+ injection is only required if the MRI was undertaken over 24 hours prior to surgery). During surgery, the sentinel nodes will be detected with the normal detector (gamma probe), the magnetometer (SentiMag) and visually (blue and black-brown colour). The detected nodes will be excised and are taken to the University of Twente for quantitative magnetometer measurements. After the measurement the lymph nodes are send to the histopathology laboratory for analysis. The analysis in the laboratory is performed routinely and does not form part of this study.

Contactpersonen

Publiek

[default]
The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with primary cutaneous melanoma scheduled for SLNB and who are clinically AJCC stage IB-IIC. - Patients available for follow-up for at least 12 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Intolerance / hypersensitivity to iron or dextran compounds.

- Patients who cannot / do not receive radioisotope for SLNB.

- Patients with an iron overload disease.
- Patients with pacemakers or other implantable devices in the chestwall.

- Intolerance / hypersensitivity to patent blue dye in the centres where this is used routinely.

- Patients who had previous surgery to the likely draining lymph node fields.

- Patients with surgical scars between the primary biopsy site and the draining lymph node field(s) that may alter the lymphatic drainage.

- Patients with pre-existing lymphedema at the primary biopsy site, either primary or secundary.

- Patients who subsequently shown to have more than stage III disease.

Exclusion criteria MRI-subprotocol:

- Presence of implantable devices (electronically, magnetically, mechanically activated. E.g: cardioverter defibrillators, cardiac pacemakers)

- Metallic splinters in the eye.

- Ferromagnetic haemostatic clips in the central nervous system.

- Claustrophobia. MRI should be avoided in the presence of relative contraindications for MRI: cochlear implants, other pacemakers, insulin pumps and nerve stimulators, prosthetic heart valves, lead wires or similar wires in-situ.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2013
Aantal proefpersonen:	176
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3809
NTR-old	NTR3997
Ander register	NL 43706.044.13 : P13-14
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten