MR lymphography and magnetic sentinel lymph node biopsy in melanoma patients measured with DiffMag

Published: 19-04-2024
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON56732

Source
ToetsingOnline

Brief title
MelaDiff; MR lymphography and magnetic sentinel lymph node biopsy

Condition

- Skin neoplasms malignant and unspecified
- Haematological and lymphoid tissue therapeutic procedures

Synonym
melanoma, skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Melanoma, MR lymphography, Sentinel lymph node, SPIO

Outcome measures

Primary outcome

- List of requirements and feedback for further optimization of the DiffMag magnetometer.

- True positive rate for a magnetic SLN detection measured by DiffMag compared to radioactive detection.

- True positive rate for a magnetic SLN detection measured by DiffMag compared to SentiMag®.

- False negative rate for a magnetic SLN detection measured by DiffMag compared to radioactive detection.

- False negative rate for a magnetic SLN detection measured by DiffMag compared to SentiMag®.

- True positive rate for a magnetic SLNB procedure measured by DiffMag compared to radioactive detection.

- True positive rate for a magnetic SLNB procedure measured by DiffMag compared to SentiMag®.

- False negative rate for a magnetic SLNB procedure measured by DiffMag compared to radioactive detection.

- False negative rate for a magnetic SLNB procedure measured by DiffMag compared to SentiMag®.

- Usability DiffMag

Secondary outcome

-Usability of LN mapping by SPIO-enhanced MRI

-Usability of LN staging by SPIO-enhanced MRI

Study description

Background summary

The sentinel lymph nodes (SLN) are the first lymph nodes (LN) to drain the tumor site and therefore the first LN to bare metastases. Hence the importance to investigate these LN for the best treatment strategy. The current method for SLN detection in e.g. melanoma and breast cancer patients uses radioactive tracer (Tc99-m). Due to the use of radioisotopes, this procedure suffers from several disadvantages such as limited availability, strict rules and regulations, degradation time in patient and radioactive load for user and patient.
To overcome the limitations of a radioactive tracer, a magnetic SLNB was developed which is facilitated by super paramagnetic iron-oxide (SPIO) nanoparticles. This potentially offers numerous benefits making surgery planning more flexible: no exposure to radiation, easy accessibility of the tracer, long shelf time, long half time in the patient. Several aspects of this magnetic procedure have been investigated in previous studies. However, currently available commercial product for perioperative detection of SPIO-enhanced LNs (Sentimag®, Endomagnetics, ltd., United Kingdom) is hampered by a relatively low detection depth, biological noise, and effects of surgical equipment. Therefore, with the current Sentimag® probe, the surgeons need to switch to plastic or carbon equipment and the system needs to be balanced prior to each measurement, which increases the surgery time by 20%.
A new and effective way to localize magnetic particles is differential magnetometry (DiffMag). This patented detection principle, developed by Magnetic Detection & Imaging (MD&I) group at University of Twente (UT), utilizes the nonlinear magnetic response of nanoparticles. An additional advantage of SPIOs is their visibility on MRI, which could map the nodes preoperatively. Especially in patients with melanomas on the abdomen or back, this would be very useful to see which lymph node stations are connected to the melanoma. In addition, studies have shown that SPIOs are absorbed into lymph nodes in different ways, depending on the presence of metastases. SPIO-enhanced MR lymphography could therefore provide an opportunity for a non-invasive preoperative assessment of nodal status.
In this pilot study we want to evaluate the clinical use of the DiffMag handheld probe, and compare the detection and usability of the DiffMag with the radioactive detection and the detection of the SentiMag for the furthur

optimazation of DiffMag. Moreover, we want to map the lymph nodes preoperatively using MR lymphography. In addition, ex vivo MRI will be used to examine the possibility of assessing the nodal status.

Study objective

In this pilot study we want to evaluate the clinical use of the DiffMag handheld probe, and compare the detection and usability of the DiffMag with the radioactive detection and the detection of the SentiMag for furthur optimazation of DiffMag magnetometer. Moreover, we want to map the lymph nodes preoperatively using MR lymphography. In addition, ex vivo MRI will be used to examine the possibility of recognizing metastases in LN.

Study design

Experimental, minimally invasive, pilot study in melanoma patients.

Intervention

Injection of Magtrace, pre- and post-injection a MRI scan will be made. During surgery, the sentinel lymph node will be traced with the SentiMag and DiffMag in addition to the conventional procedure.

Study burden and risks

This research will not be beneficial to the subject. However, the results of the study will be used to optimize the SLNB procedure. The study outcomes are used to progress to a radiation-free and minimally invasive procedure. The benefits are concerning the future patient group, including not only melanoma patients, but also breast cancer patients and potentially all solid cancers eligible for SLNB.
The study won*t delay diagnosis or treatment, the MRI scans and Magtrace injection will be scheduled as much as possible with regular hospital visits. The possible delay of the surgical date will be in the order of days and the time between surgery and treatment will always be according to the national guidelines. The extra time will be a maximum of 15-20 minutes.
The only burden is the extra injection of iron containing particles, with an effective amount of iron which is lower than the amount of iron injected safely in previous studies. The patient will not experience any side effects from the two in-vivo MRI scans in this study. Prior to MRI, patients follow the standard questionnaire that applies to all other MRI examinations in the hospital. With the questionnaire will be determined if the patient is suitable for the MRI examinations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients with melanoma of the upper or lower extremities scheduled for SLNB

Exclusion criteria

1.Patients incapable of giving informed consent for participation to the study;
2.Intolerance / hypersensitivity to iron or dextran compounds;
3.Pregnant or lactating patients
4.Patients having a pacemaker implanted.
5.Patients non eligible for MRI investigation (pacemakers or other implantable

devices in the chest wall and/or lower body, claustrophobic, etc.)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2024
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Injection of Magtrace (CE);detection with SentiMag (CE) or DiffMag (no-CE) (Magnetometers)
Registration:	No

Ethics review

Approved WMO

Date:	19-04-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05569707
CCMO	NL79537.100.23