Exploring an alternative pre-operative sentinel lymph node mapping method using a Magnetic tracer and MRI for potential use in melanoma patients: Imaging subprotocol in healthy participants

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON49990

Source
ToetsingOnline

Brief title
TRACIE Study

Condition

- Skin neoplasms malignant and unspecified

Synonym
Melanoma, skin cancer

Research involving

Human

Sponsors and support

Primary sponsor: Heelkunde
Source(s) of monetary or material Support: -

Intervention

Keyword: Magnetic tracer, Melanoma, MRI, Sentinel lymph node procedure

Outcome measures

Primary outcome

Dosages of Magtrace® (ml), massage duration (minutes), route of administration

and MRI settings (sequences) will be defined stepwise. Time of lymphatic SPIO

uptake and appearance of LNs will be defined for different injection regions.

Secondary outcome

NA

Study description

Background summary

Sentinel lymph node biopsy is crucial in the management of malignant melanoma treatment and is currently performed by pre-operatively inject a colloid nanomaterial labeled with Technetium (99mTc) as radioactive tracer. Subsequently, a lymphoscintigraphy (LS) and single-photon emission computed tomography/computed tomography (SPECT/CT) will be performed. Intra-operatively, Blue dye (BD) will be injected to improve the visualization of the lymphatic tract.
Superparamagnetic iron oxide (SPIO) is a novel technique using a magnetic tracer (Magtrace® (Endomagnetics Ltd.)) and several studies showed that SPIO is non-inferior to dual tracing with 99mTc and BD in breast cancer patients. SPIO is expected to be non-inferior to dual tracing with 99mTc and BD in melanoma patients. However, further research is needed to demonstrate the use of Magtrace in pre-operative MRI scanning. Magnetic tracers have an extended time span in contrast to isotopes, which provides more opportunities in scheduling scans and might therefore optimize the pre-operative care pathway.

Additionally, it is a non-radioactive alternative which is in favor of both patients and healthcare personnel.

A pre-operative MRI protocol will be developed by including healthy participants of the research team in a small study. Injection sites, Magtrace dosage, massage duration and artefact transformation will be evaluated. Depending on findings, two or three test days will be scheduled.
Acquired knowledge will serve to design a feasibility study, including a larger group of melanoma patients.

Study objective

The primary objective of this study, including healthy subjects, is to develop a pre-operative MRI protocol for the localization of SLNs in melanoma patients. Acquired knowledge will serve to design a feasibility study, including a larger group of melanoma patients.

Study design

This small prospective subprotocol study will adopt a step-by-step approach to develop a pre-operative MRI protocol for the localization of SLNs in melanoma patients. Testing will be performed according to a predefined protocol, however, the protocol might be adapted considering findings in first participants.

Study burden and risks

The aim of the study is to develop a pre-operative MRI protocol, eventually applicable in melanoma patients to identify SLN prior to SLNB. Magtrace® is formerly approved and used in breast cancer patients. Except one hospital visit, no burden and risks are associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Healthy participants;
Participants should be *18 years of age at the time of consent;
Participants should be willing to provide informed consent.

Exclusion criteria

Known intolerance/hypersensitivity to iron, dextran compounds or Magtrace® itself;
Standard MRI exclusion criteria:
- Implantable (electrical) devices (e.g. pacemaker, cochlear implants, neurostimulator);
- Any other metal implants
- Claustrophobia;
- MR-incompatible prosthetic heart valves;
- Tattoos inked with metallic dye.
Participants who refuse to provide informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2021
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	26-07-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL78112.096.21