Exploring an alternative pre-operative sentinel lymph node mapping method using a Magnetic tracer and MRI for melanoma patients

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

Summary

ID

NL-OMON51995

Source
ToetsingOnline

Brief title
SCARLETT 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: Deels door de onderzoeker en deels door Sysmex,Sysmex

Intervention

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

Outcome measures

Primary outcome

The diagnostic accuracy of SPIO/MRI and LS+SPECT/CT and 99mTc to identify SLN will be expressed as sensitivity and specificity, and positive and negative predictive values, including their 95% exact binomial confidence intervals. MRI image analyses will be performed by two independent professionals.

Secondary outcome

The diagnostic accuracy of SPIO/magnetometer and 99mTc and Gamma probe will be expressed as sensitivity and specificity, and positive and negative predictive values, including their 95% exact binomial confidence intervals.

Comparison between 99mTc injection + LS + SPECT/CT time vs SPIO injection + MRI

Number of days between preoperative MRI and SLNB.

Moreover, the MRI workflow protocol will be validated and potentially optimized.

Study description

Background summary

Sentinel lymph node biopsy (SLNB) 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. Intra-operatively, Patent Blue (PB) will be injected to improve the visualization of the lymphatic tract. However, current pre-operative SLN

mapping technique, is associated with disadvantages as radiation exposure for both patients and health care staff and logistic challenges, because of time constraints due to short half-live time of 99mTc.

Superparamagnetic iron oxide (SPIO) is a novel, non-radioactive technique using a magnetic tracer (Magtrace® (Endomagnetics Ltd.)) to identify SNLs. Several studies showed that SPIO is non-inferior to dual tracing with 99mTc and PB in breast cancer patients. SPIO is expected to be non-inferior to dual tracing with 99mTc and PB in melanoma patients. However, further research is needed to demonstrate the use of SPIO in pre-operative MRI scanning.

Study objective

The primary objective of this study is to evaluate the feasibility and diagnostic accuracy of pre-operative MRI scanning using SPIO compared to lymphoscintigraphy (LS) and single-photon emission computed tomography/computed tomography (SPECT/CT) using 99mTc for identifying SLN status in melanoma patients. A secondary objective is to assess the feasibility and diagnostic accuracy of SPIO/magnetometer (Sentimag®, Endomagnetics Ltd.) in comparison with gold standard (99mTc) in SLN procedures in melanoma patients.

Study design

A prospective single-arm feasibility study will take place at the department of Surgical oncology of Zuyderland Medical Center Sittard, the Netherlands. All melanoma patients with an indication for SLN procedure will undergo lymphatic mapping with 99m Tc and SPIO.

Study burden and risks

The aim of the study is to evaluate the feasibility and diagnostic accuracy of SPIO/MRI in SNL procedures in melanoma patients. Magtrace® is formerly approved and used in breast cancer patients. Except one extra hospital visit, no burden and risks are associated with participation.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients >=18 years of age at the time of consent;
Histological confirmed melanoma (patient must have primary cutaneous melanoma with
Breslow thickness >= 0.8-2.0mm with or without ulceration or <0.8mm with ulceration (pT1b - pT2b, AJCC 8th edition));
Indication for wide local excision (margin 1 cm) and SLN procedure;
Patients should be willing and able to provide informed consent.

Exclusion criteria

Intolerance/hypersensitivity to 99mTc-nanocolloid, PB, iron or dextran compounds;
Iron overload disease;
Pregnant or breast-feeding women;
Previous surrounded lymph node surgery;
Patients with head and neck melanomas;
Standard MRI exclusion criteria;
- Implantable (electrical) devices (e.g. pacemaker, cochlear implants, neurostimulator);
- Any other metal implants;
- Claustrophobia;

- MR-incompatible prosthetic heart valves;
Patients who are unable or 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:	Recruiting
Start date (anticipated):	03-02-2023
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	04-11-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-12-2022
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	26-02-2024

Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-03-2024
Application type:	Amendment
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	NL78185.096.21