Detection of the sentinel lymph node in oral cancer using iron oxide nanoparticles, MRI and a magnetometer: a pilot study.

Published: 19-12-2017
Last updated: 12-04-2024

Determining the feasibility of SLN detection in the neck of oral cancer patients using a magnetic tracer (Sienna+®), MRI and hand-held magnetometer (SentiMag®).When the magnetic approach of sentinel node detection is found to be feasible, the main...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON48567

Source
ToetsingOnline

Brief title
MagLocHN

Condition

- Head and neck therapeutic procedures

Synonym
oral cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: STW-KWF 15194

Intervention

Keyword: magnetic detection, oral cancer, sentinel lymph node

Outcome measures

Primary outcome

* The proportion of patients in which the SLNs could be detected (detection rate) using the magnetic method.

* The proportion of sentinel nodes detected per patient during the SNB (in vivo) and after END, thus excised specimen (ex vivo).

* The false-negative rate of detected SLNs based on the histopathological analysis.

Secondary outcome

* The proportion of sentinel nodes which could be localized per patient on the MRI;

* Estimation of maximal distance needed to detect Sienna signal by SentiMag;

* SNB duration/ total duration time.

Study description

Background summary

The sentinel node biopsy (SNB) is a minimal invasive procedure to evaluate the occurrence of occult metastases for tumors that metastasize via the lymphatic system. Within the standard SNB procedure, a radioactive tracer is used for localization and detection of sentinel lymph nodes (SLNs). Unlike in breast cancer and melanoma, an accurate method for nodal staging is not available for all cancer (sub)types of which head and neck cancer is one of the most complex types. There is a need to find another tracer/ route which has a better sensitivity in localization and detection of floor of mouth-tumors.

For the SNB procedure in the axilla (breast cancer), good results were found with the use of a magnetic route (SentiMag®, magnetic detector, and Sienna+®, magnetic tracer).
In the IronNanoLoc program, we aim to develop a patient friendly and reliable procedure for SLN detection and staging for a patient group that presently cannot fully benefit from such a high-quality SLN-biopsy procedure, that is much less invasive than the END that is presently used in this H&N patient group. The first step in the IronNanoLoc program is to start with a pilot study to test the feasibility of the magnetic route, using SentiMag® and Sienna+®. If it*s shown feasible, research will be done to improve the magnetic approach and the radioactive and magnetic route will be compared in a subsequent study.

Study objective

Determining the feasibility of SLN detection in the neck of oral cancer patients using a magnetic tracer (Sienna+®), MRI and hand-held magnetometer (SentiMag®).

When the magnetic approach of sentinel node detection is found to be feasible, the main study will be performed. In this main study, the conventional SNB and the magnetic approach for SNB in the head and neck area are compared.

Study design

An interventional, minimally invasive pilot study embedded in standard patient care (elective neck dissection (END)).

Intervention

A peritumoral injection with magnetic/ iron oxide nanoparticles (Sienna+) is given, followed by an pre-operative MRI to localize the SLN. During elective neck dissection (standard care), an additional SNB is performed using a hand-held magnetometer (SentiMag®) and the already injected Sienna+. Surgery will be completed following standard care (elective neck dissection and tumor resection).

Study burden and risks

Burden: Additional local interstitial injection with magnetic tracer (Sienna+). Additional MRI-scan pre-operative and post-operative. Risks & benefits: no risks and benefits are expected for the participants, after the SNB, elective neck dissection will be completed and the magnetic tracer is dissected too, so participants finally undergo standard care and treatment is not delayed by the study. A relative prolongation of operation room time is expected, however due to finally given standard care, operation risks are not increased.

It is important to perform the study in patients with oral cancer, to see if the magnetic application is feasible for detection of SLN in the neck and can overcome the shortcomings of the conventional SNB in this patient group. Therefore, benefits of the magnetic SLN detection are concerning the future patient group, for reliable staging and patient friendly and highly personalized treatment by eliminating the need to surgically remove all LNs in this region in all patients.

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

- Patients diagnosed with T1-T2 oral cancer scheduled for END and who have clinically and radiologically at maximum cN1, <15mm and not contains necrotic tissue;

- Willing to & able to write informed consent from the subject prior to participation.
- Willing to & capable of following study procedures
- Is older than 18 years
- Speaks and understand the Dutch language

Exclusion criteria

- Positive result of ultrasound fine needle aspiration, for nodes >15mm and/or necrotic tissue;
- Intolerance/ hypersensitivity to iron or dextran compounds or Sienna+;
- Intolerance/ hypersensitivity to lidocaine;
- Patients with an iron overload disease;
- Patients with non-palpable malignancies;
- Pregnant patients;
- Patients with pacemakers or other implantable devices in the upper body.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	SentiMag and Sienna+
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-12-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2019
Application type:	Amendment
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
CCMO	NL63042.044.17