Sentinel lymph node localization of oral cancer using magnetic detection.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27348

Source
Nationaal Trial Register

Brief title
MagLocHN

Health condition

Sentinel node biopsy (SNB), sentinel lymph node (SLN), oral cancer, magnetic detection.
DUTCH: poortwachterklier procedure, mondholte kanker, magnetische detectie

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: STW-KWF

Intervention

Outcome measures

Primary outcome

To investigate the feasibility of the magnetic approach in detection of the SLNs during SNB in the neck of patients with T1-T2 cancer

Secondary outcome

- Detectionrate

- Compare results of MRI, surgery and pathology.

Study description

Background summary

Sentinel node biopsy (SNB) is a highly sensitive procedure for lymph node (LN) staging in head and neck cancer, particularly in T1-T2 oral cancer patients (1). However, nowadays sentinel lymph nodes (SLN, lymph nodes with the highest risk for containing metastasis) cannot always be detected by currently available radioactive tracer due to the complex head and neck anatomy and the ‘shine through’ phenomenon of radioactive tracers due to the close spatial relation with the primary tumor, e.g. floor of mouth. Magnetic tracers may overcome the problems of currently used (radioactive) tracers. The feasibility of magnetic SLN detection in head and neck cancer patients, is tested with a first-generation magnetic detector. The magnetic application to SNB enables more reliable staging and patient friendly and highly personalized treatment by eliminating the need to surgically remove all LNs in this region in all patients (2).

1. Govers TM, Hannink G, Merkx MAW, Takes RP, Rovers MM. Sentinel node biopsy for squamous cell carcinoma of the oral cavity and oropharynx:
A diagnostic meta-analysis. Oral Oncol. Elsevier Ltd; 2013;49(8):726–32.

2. Murer K, Huber G, Haile S, Stoeckli S. Comparison of morbidity between sentinel node biopsy and elective neck dissection for treatment of the n0 neck in patients with oral squamous cell carcinoma. Head Neck. 2011;33(9):1260–4.

Study objective

Sentinel node biopsy (SNB) is a highly sensitive procedure for lymph node (LN) staging in head and neck cancer, particularly in T1-T2 oral cancer patients. However, nowadays sentinel lymph nodes (SLN, lymph nodes with the highest risk for containing metastasis) cannot always be detected by currently available radioactive tracer due to the complex head and neck anatomy and the ‘shine through’ phenomenon of radioactive tracers due to the close spatial relation with the primary tumor, e.g. floor of mouth. Magnetic tracers (superparamagnetic nano particles, SPIO) may overcome the problems of currently used (radioactive) tracers. The feasibility of magnetic SLN detection in head and neck cancer patients, is tested with a first-generation magnetic detector. The magnetic application to SNB enables more reliable staging and patient friendly and highly personalized treatment by eliminating the need to surgically remove all LNs in this region in all patients.

Study design

When the first 5 inclusions are finished results of the post-op MRI will be analyzed and determine if SPIO dose needs to be adjusted and if upcoming inclusions also need an post-op MRI.

Intervention

Peritumoral injection of SPIO, after Xillocaïne spray, and followed by an MRI to localize the SLN, the day before surgery. Also trancutaneous detection of trapped SPIO in SLN will be performed using a magnetometer.

At the day of surgery a SNB is performed during standard elective neck dissection. The SLN will be intraoperatively detected using a magnetometer.

Four-six weeks after surgery an extra MRI might be made.

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2018
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-12-2017
Application type:	First submission

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
NTR-new	NL6656
NTR-old	NTR6890
Other	STW-KWF/NWO 15194 : METC Twente P17-23, NL63042.044.17

Study results