

Sentinel lymph node localization of oral cancer using magnetic detection.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27348

Bron

Nationaal Trial Register

Verkorte titel

MagLocHN

Aandoening

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

Ondersteuning

Primaire sponsor: University of Twente

Overige ondersteuning: STW-KWF

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the feasibility of the magnetic approach in detection of the SLNs during SNB in

Toelichting onderzoek

Achtergrond van het onderzoek

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, Merks 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Peritumoral injection of SPIO, after Xillocaine spray, and followed by an MRI to localize the SLN, the day before surgery. Also transcutaneous 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd

Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 01-01-2018
Aantal proefpersonen: 10
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 06-12-2017
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6656
NTR-old	NTR6890

Ander register STW-KWF/NWO 15194 : METC Twente P17-23, NL63042.044.17

Resultaten