Radiation-free, magnetic, sentinel lymph node detection and evaluation

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON27580

Bron
NTR

Verkorte titel
LowMag

Aandoening

Breast cancer, borstkanker
Results are also applicable to melanoma, prostate cancer.
Resultaten zijn ook toepasbaar op melanoom en prostaatkanker.

Ondersteuning

Primaire sponsor: University of Twente, Enschede, the Netherlands
Overige ondersteuning: STW (Stichting Technologische Wetenschappen), initiatior and participant (Medisch Spectrum Twente)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The proportion of sentinel nodes correctly detected with the magnetic method compared to the combined technique (visually and/or using the gammaprobe).
2. The proportion of patients in which the sentinel lymph nodes could successfully be detected (detection rate) using the magnetometer.
3. The number and percentage of sentinel lymph nodes correctly diagnosed to be metastatic using ex vivo MRI „³ sensitivity;
4. The number and percentage of sentinel lymph nodes correctly diagnosed to be non-metastatic using ex vivo MRI specificity.

Toelichting onderzoek

Doel van het onderzoek

The sentinel lymph nodes (SLN) are the first lymph nodes to drain the tumor site and therefore the first lymph nodes to bare metastases. Hence the importance to investigate these lymph nodes to define the best treatment strategy. Currently in a.o. breast cancer and melanoma patients, the sentinel lymph nodes are intraoperatively detected, both visually and by using a gamma probe, following the subsequent injections of radioactive tracer (Tc 99-m) and blue dye (Patent Blue). Histopathological investigation of the resected sentinel lymph nodes should then confirm the presence or absence of metastases. The conventional methods for sentinel lymph node biopsy suffer from disadvantages, such as the use of radioactive materials and the fact that node-positive patients require multiple surgical procedures. At the NeuroImaging (NIM) group of the University of Twente, we investigate a magnetic, radiation-free, procedure for sentinel lymph node detection and evaluation. Several aspects of this procedure have been investigated in separate studies. Though results were promising, showing a detection rate of the sentinel node non-inferior to the existing technique and proving the feasibility to visualize the sentinel node in preoperative MRI, the doses and volume of the injected magnetic tracer (SuperParamagnetic Iron Oxide particles, SPIO), were relatively high. The high dose of iron potentially leads to difficulties in evaluating lymph nodes with small metastases and to substantial skin staining. Additionally, the high volume of injected tracer might in some cases lead to a non-physiological uptake of iron in the lymph vessels, reducing the reliability for detecting (solely) sentinel lymph nodes. In this study, the aim is to investigate the feasibility of using low dose SPIO (50x lower than the previously safely used dose) for both evaluation and detection of the sentinel lymph node in breast cancer patients.

Onderzoeksopzet

The study outcomes will be evaluated after every ten successful measurements, after every 5 MRI investigations on specimen containing macrometastases, after every 5 MRI investigations on specimen not containing metastases and at the end of the study.

Onderzoeksproduct en/of interventie

A low dose peritumoral injection of Sienna+ (2x 0.5 mL), with a total dose of approximately 1.1 mg iron.

Contactpersonen

Publiek

MIRA Institute for Biomedical Technology and Technical Medicine
University of Twente
P.O. Box 217
M. Heijblom
Enschede 7500 AE
The Netherlands
+31 (0)53 4893877

Wetenschappelijk

MIRA Institute for Biomedical Technology and Technical Medicine
University of Twente
P.O. Box 217
M. Heijblom
Enschede 7500 AE
The Netherlands
+31 (0)53 4893877

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult, clinically (palpation and ultrasound) node negative, patients that are diagnosed with invasive breast cancer or high grade ductal carcinoma in situ and that are scheduled for a two-day SLNB procedure and that gave informed consent for participation to the study;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1.Patients incapable of giving informed consent for participation to the study;

2.Intolerance / hypersensitivity to iron or dextran compounds;

3.Patients that have received neoadjuvant chemotherapy in the period of 5 years prior to this study.

4.Pregnant or lactating patients

5.Patients having a pacemaker implanted.

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2014
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	NL4698
NTR-old	NTR4903
Ander register	NL49285.044.14 : METC Twene P14-32

Resultaten