Magnetic marker localization for non-palpable breast cancer

Gepubliceerd: 18-07-2019 Laatst bijgewerkt: 18-08-2022

The magnetic marker is comparable to the I-125 marker regarding retrieval rate

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

Samenvatting

ID

NL-OMON23325

Bron
Nationaal Trial Register

Verkorte titel
MAG10

Aandoening

Breast Cancer

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is retrieval rate of the magnetic marker using only the magnetic probe.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: When conducting breast-conserving surgery, accurate tumor localization is challenging when the tumor is not palpable. Existing techniques for tumor localization, such as wire guided and radioactive seed localization yield acceptable results but have considerable disadvantages, like organizational and legislative aspects and high patient discomfort. Recently, a new technique has been developed to overcome these issues; localization through a magnetic marker and probe.
Objective: To test feasibility of magnetic marker localization as a technique to operate on non-palpable breast cancer and to determine radiologist and surgeon satisfaction.
Study design: A prospective cohort pilot study.
Study population: 10 women, aged 18 years or older, with non-palpable, biopsy confirmed, unifocal breast cancer eligible for breast-conserving surgery that have not undergone any neo-adjuvant treatment.
Intervention: A radiologist will first implant a magnetic marker and then a radioactive marker using image guidance. During surgery, the surgeon will locate the tumor using the magnetic probe and only use the gamma probe when it is deemed irresponsible to continue with the magnetic probe.
Main study parameters/endpoints: The primary outcome measure is retrieval rate of the magnetic marker using only the magnetic probe. Secondary outcome measures are radiologist and surgeon satisfaction, determined through questionnaires and resection margins, collected from pathology reports.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Implanting one extra marker in addition to the standard care marker, implanted through the same incision, without extra risks or hospital visits for the patient.

Doel van het onderzoek

The magnetic marker is comparable to the I-125 marker regarding retrieval rate

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

All patients will receive a radioactive iodine seed (Bard Medical, Covington, USA) as per standard care, and the magnetic marker (Magseed, Endomag, Cambridge, UK). A radiologist will first implant the magnetic marker to ensure optimal placement and will then implant the iodine seed. Both markers will be placed under ultrasonic guidance and in the same session. After implantation, the accuracy of location will be assessed through mammography.
The surgery will be performed within 30 days of implantation. During the surgery, the magnetic probe (Sentimag probe, Endomag, Cambridge, UK) will be available for localizing

the marker. Polymer tools will be provided as to not interfere with the magnetic probe. The gamma probe (Neoprobe, Mammotome, Cincinnati, USA) will be available; however, it will only be used as a back-up for when localization through the magnetic probe is not possible or when the surgeon feels unsure about the location determined with the magnetic probe. Once the lesion is resected, the gamma probe will be used to confirm the presence of the iodine seed in the resected tissue. Post-operatively, patients will receive standard follow-up care.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

I. Female patients aged 18 years or older;
II. Patients have biopsy-confirmed, unifocal, non-palpable breast cancer;
III. Patients are eligible for breast-conserving surgery;
IV. Patients did not undergo any neo-adjuvant treatment;
V. Patients are willing and able to provide written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

I. The patient has a pacemaker.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	29-07-2019
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-07-2019
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	NL7881
Ander register	CME LUMC : P19.016

Resultaten