Nonradioactive surgical guidance with radiofrequency identification technology for locating nonpalpable breast lesions

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RFID localization for nonpalpable breast lesions is a feasible, non-radioactive alternative for I125-seed localization with regard to the percentage of radical excisions (radical, focally irradical, more than focally irradical) and re-excision rate.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22145

Bron
Nationaal Trial Register

Verkorte titel
RFID Localizer 1 Trial

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: Hologic
Overige ondersteuning: Hologic

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is the percentage radical excisions. Margins are classified as tumor free, focally irradical and (more than focally) irradical, see figure below. Both focally irradical and more than focally irradical excisons are considered irradical excisions. The percentage of re-excisions following irradical excisions is recorded.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Breast conserving surgery is an effective and safe method to treat early breast cancer. Accurate intraoperative lesion localization is essential to remove the lesion with adequate surgical margins and to avoid unnecessary resection of healthy tissue in order to provide a good cosmetic result without compromising survival or local recurrence. Preoperative wire localization and radioactive seed localization are accepted standard methods to guide surgical excision of nonpalpable breast lesions. However, these techniques present a number of limitations. Radiofrequency technology may offer a viable alternative method for localizing nonpalpable breast lesions in patients undergoing breast surgery.
Objective: To demonstrate feasibility of RFID surgical guidance for nonpalpable breast lesions with regard to percentage radical excisions and re-excision rate.
Study design: Multicenter prospective cohort study.
Study population: University Medical Center / Diakonessenhuis Utrecht: ≥100 women, ≥ 18 year old, with a nonpalpable histologically proven in situ or invasive breast cancer lesion requiring breast conserving surgery. Medisch Spectrum Twente Enschede: ≥100, ≥ 18 year old, with a nonpalpable histologically proven in situ or invasive breast cancer lesion requiring breast conserving surgery.
Main study parameters/endpoints: Percentage of radical excisions and the re-excision rate.

Doel van het onderzoek

RFID localization for nonpalpable breast lesions is a feasible, non-radioactive alternative for I125-seed localization with regard to the percentage of radical excisions (radical, focally irradical, more than focally irradical) and re-excision rate.

Onderzoeksopzet

Start RFID Localizer 1 Trial: september 2019
Expected completion of target inclusion: end 2020

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in the cohort study, a subject must meet all of the following inclusion criteria:
 1. Female patient ≥ 18 years of age
 2. Nonpalpable histologically proven in situ or invasive breast cancer that requires excision
 3. Patient is scheduled for breast conserving surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in the cohort study:
 1. Breast lesion is located deeper than 7 cm from the skin when lying supine
 2. Multicentric breast cancer
 3. Pregnancy or lactating
 4. Subject is unable to understand, read and sign the study specific informed consent form after the nature of the study has been fully explained to her

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-09-2019
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8019
Ander register	METC UMCU : 19/133

Resultaten