Premarket study to assess safety and performance of the Orion Magnetic Localization System for breast cancer

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

Samenvatting

ID

NL-OMON24152

Bron
Nationaal Trial Register

Verkorte titel
Orion-1

Aandoening

Breast Cancer

Ondersteuning

Primaire sponsor: Sirius Medical Systems B.V.
Overige ondersteuning: Industry; Sirius Medical Systems

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1) Performance. Number and percentage of procedures in which ORION SEEDS is present on post-operative specimen X-ray and only the ORION detector is used during surgery [=>95%]
2) Safety. Adverse events as assessed by MedDRA.Number and percentage of patients who experienced a device-related adverse event. [No SADEs]

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Surgeons require localization technologies to accurately remove non-palpable or clinically occult soft-tissue lesions, but current solutions are hampered by either logistical limitations (Wire Guided Localization) or high operational risks (Radioactive Seed Localization). Sirius Medical Systems has developed a novel, non-radioactive and simple localization technology (Orion) that aims to replace the current solutions.
Objective: To show that the Orion Magnetic Localization System is safe and performs as intended for the surgical removal of early stage breast cancer.
Study design: premarket, open label, monocentre, prospective clinical interventional trial
Study duration: 4 months
Study start: July 1st, 2019 (projected)
Study population: female adult breast cancer patients
Inclusion criteria: diagnosed with a single, pathologically confirmed unifocal breast lesion (Ductal Carcinoma in Situ (DCIS) or invasive) and indicated for primary breast conserving surgery requiring preoperative localization with a single (radioactive) seed.
Exclusion criteria: Patients should not be pregnant or lactating; receive neo-adjuvant chemotherapy; have an ICD or other active implant such as a pacemaker less than 5cm away from the intended target location; have a proven infection or hematoma at or close to the intended target location; be scheduled for immediate breast reconstruction (within the same surgical procedure); expected to require an MRI scan of the breast area in the period between implantation and surgery
Intervention: patients will receive pre-operative ultrasound-guided localization of the tissue of interest using the investigational Orion Magnetic Seed. Surgery will be performed using the Orion Magnetic Detector that detects and provides real-time distance feedback towards the Orion Magnetic Seed.
In the first three cases for each surgeon (Phase 1), the investigational device will be combined with the standard of care (radioactive seed) to use as training cases before proceeding to the formal investigational cases (Phase 2).
Number of patients: 30 (6 training cases, 24 Orion-only cases)
Main study parameters/endpoints: Performance: number of seed retrievals using only the Orion Magnetic Detector and no back-up technology [≥95%]. Safety: number of device-related serious adverse events [none].
Follow-up: 1 month
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: burden to first three (phase 1) training cases per surgeon (total of 6) consists of an additional puncture at the radiology department during a routine procedure.

Burden to Orion-only (phase 2) cases is limited. The Orion Magnetic Localization procedure is similar to the standard of care. These cases will be requested to score their experience with the technology using a single question.
Risks of participation are limited, the Orion Magnetic Seed implant has a biocompatible titanium exterior. A previous, comparable magnetic seed developed by Sirius was tested and found safe and feasible in over 70 procedures.
Benefits for participating for regular cases include the avoidance of harmful ionizing radiation.

Doel van het onderzoek

The primary hypothesis is that after a training period surgeons are able retrieve the Orion Magnetic Seed using the Orion Magnetic Detector without requiring another localization technology in ≥95% cases, andthere are no device-related serious adverse events (SAEs) reported.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

Patients in the first training phase will receive the investigational technology (Orion Magnetic Localization) alongside the standard of care Radioactive Seed Localization. Patients in the second Orion-only phase will receive only Orion Magnetic Localization.

In Orion Magnetic Localization, the tissue of interest is marked using the Orion Magnetic Seed up to 30 days prior to surgery at the department of radiology using Ultrasound guidance. During surgery, the surgeon uses the Orion Magnetic Detector to detect the seed and guide surgery. The tissue of interest is removed together with the Orion Magnetic Seed.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient is willing and able to provide informed consent for the investigation and to comply to the schedule of assessments of the clinical investigation
2. Patient is at least 18 years of age
3. Patient is diagnosed with a single, pathologically confirmed unifocal breast tumour (DCIS or invasive)
4. The tumour is ultrasound visible
5. Patient is indicated for primary breast conserving surgery
6. Patient is indicated for preoperative localization using a single (radioactive) seed

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patient is pregnant
2. Patient is receiving neo-adjuvant chemotherapy
3. Patient has an ICD or other active implant such as a pacemaker less than 5cm away from the intended target location
4. Patient has a proven infection or hematoma at or within 5cm of the intended target location
5. Patient is scheduled for immediate breast reconstruction (within the same surgical procedure)
6. Patient is currently participating in, or has recently exited from, or plans to be enrolled in another clinical investigation which may affect the outcomes of the current clinical investigation, as assessed by the discretion of the investigator
7. Patient is expected to require an MRI scan of the breast area in the period between implantation and surgery
8. The expected time between placement of Orion Magnetic Seed and surgery exceeds 30 days

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:	01-07-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	25-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48270
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7630
CCMO	NL69460.028.19
OMON	NL-OMON48270

Resultaten