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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24152

Source
Nationaal Trial Register

Brief title
Orion-1

Health condition

Breast Cancer

Sponsors and support

Primary sponsor: Sirius Medical Systems B.V.
Source(s) of monetary or material Support: Industry; Sirius Medical Systems

Intervention

Outcome measures

Primary outcome

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]

Secondary outcome

In situ time Days between implantation and surgery [all cases <30 days] Accuracy of placement - Average distance between centre of SEED and centre of lesion measured on two-way mammography in mm [descriptive] Sonographic Tumour depth - Minimum distance between skin and tumour border on ultrasound imaging (mm) [descriptive] Sonographic Tumour size - Shortest and longest axis of tumour on ultrasound (mm) [descriptive] Radiologist Satisfaction - Satisfaction as measured on a questionnaire [see Appendix A] Operative time - Minutes from first incision until excision of specimen [descriptive] Transcutaneous detection - Number and percentage of procedures in which a reliable signal is measured on the intact skin preoperatively. Also note the value. [≥95% of cases] Seed Confirmation - Seed detected in excised specimen using ORION detector [descriptive] Surgeon Satisfaction - Satisfaction as measured on a questionnaire Patient Convenience - Patient convenience reported measured using a single quesiton Margin Status - Margin status defined per NABON Dutch national guidelines [descriptive] Reoperation - Second, separate surgical procedure of same lesion or area indicated after multidisciplinary discussion [descriptive]

Study description

Background summary

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.

Study objective

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.

Study design

?

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48270

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results