MagSNOLL multicenter Study

No registrations found.

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

Summary

ID

NL-OMON26455

Source
Nationaal Trial Register

Brief title
MagSNOLL multicenter Study

Health condition

Patients (male or female) with histologically proven non-palpable breast cancer visible on ultrasound and suitable for SLNB

Sponsors and support

Primary sponsor: Guy's and St Thomas Hospitals, UK
Source(s) of monetary or material Support: Guy's and St Thomas Hospitals, London United Kingdom
University of Twenthe, Enschede The Netherlands

Intervention

Outcome measures

Primary outcome

Primary endpoint: 1) Successful localisation (Confirmation that “peak” SentiMag TM readings correspond to centre of the excised lesion on specimen radiograph).

Secondary outcome

Secondary endpoints: 1) Margin involvement 2) re-operation rates 3) SLNB success rates (magnetic technique +/- blue dye and standard technique) 4) Volume of specimen 5) Weight of specimen 6) Operative time 7) Complications 8) Radiological localisation time 9) Patient recorded outcome measures. 10) Cost 11) Accuracy of MRI for the localization of SLNs.

Study description

Background summary

The MagSNOLL Multicentre Trial is a phase II paired equivalence trial. The study will be coordinated from Kings's College Londen (Guy's Hospital) by the Chief Investigator Mr. Michael Douek. The trial aimed to recruit 160 patients.
Patients will receive a radioisotope injection and a intra tumoral Sienna+ injection. In cetres that also participate in the MRI sub protocol, patients will undergo a pre-operative MRI after the injection of Sienna+. At the Medisch Spectrum Twente pre-operative MRI scans will be performed depending on the availability of the MRI scanning slots.

Intra-operatively, patients will receive an intradermal injection of patent blue (Guerbet, Paris). The occult lesion and all sentinel nodes detected intra operatively using the the SentiMAG will be excised and sent separately to the pathology department. Then the standard technique, the gamma probe, is used to see whether there is activity remained behind. This tissue will be removed and sent to the pathology department separately. The removed breast tissue will be checked for the presence of the clip marker, at the radiology department.

All lymph nodes will be assessed histologically and the nodal status will be related back to the SLNB detection rate with each technique.
Patients will be followed post-operatively (7-14 days after surgery) to assess if staining occurs or for any other adverse event. If staining is present, photographs will be taken. Further follow-up is at 3 months and at 1 year. Patients will be followed up for a total of 5 years, in accordance with current local policies.

Study objective

The current gold standard for the treatment of occult lesions is excision by wire- guided localization (WGL). (section 1 in protocol) However, despite being the current gold standard, the process has drawbacks. The flexible wire can be difficult for the surgeon to palpate, resulting in difficulty locating the tip. This could lead to incomplete lesion excision and re-excision rates of up to 43 percent as demonstrated in randomized controlled trials

The gold standard for sentinel node detection is the 'combined technique', using both blue dye and radioisotope injection. The combined technique has major drawbacks. The use of radioisotope exposes patients and healthcare workers to radiation, is heavily controlled by legislation (both on specific training for operators and subsequent disposal of surgical waste), and provides poor pre-operative imaging. As a result, some centers have stopped undertaking routine pre-operative lymphoscintigraphy.

Intra-operative blue dye injection can obscure the surgical field, frequently leaves skin residue (tattoo stain) which can take months to fade and has a 1:1000 risk of allergic reaction. There is thus a clinical need to develop new techniques for detecting sentinel nodes without these drawbacks.

The MagSNOLL multicentre study will evaluate a new technique for sentinel lymph node biopsy (SLNB) against the standard technique. The new technique uses 2 devises; a intra tumoral injection of a magnetic tracer (sienna+) and the use of a hand-held device (a magnetometer - The SentiMAG) to detect the sentinel node(s) intraoperatively (section 2 in the protocol). The magnetic tracer does not have the disadvantages related to the use of a radioactive tracer. Besides, the brown-black appearance of the iron nano particles act as a visual stain without obscuring the operating field.

The use of MRI imaging might obviate the poor pre-operative imaging results associated with lymphoscintigraphy (section 2.4 in the protocol). The MRI subprotocol will evaluate pre-operatively MRI (with magnetic tracer) for sentinel node imaging and characterization. The aim of the subprotocol is to evaluate MRI for both pre-operative and intra-operative detection of lymph node metastasis.

Magnetic tracers and hand-held magnetometer might just be what surgical researchers have been looking for as a tool that could be used to act on what is seen on MRI. MRI and SPIO directed SLNB would offer a technique to image the patient preoperatively with high spatial resolution and retrieve sentinel nodes without the use of radioisotopes.

Study design

Successful localization of the excised lesion, with Sienna+ and SentiMag. 2 measurements a week till 60 measurement are completed successfully.

Accuracy of MRI for the localization of SLNs. With MRI max 24 ours before surgery.

Intervention

In addition to the Sienna+ injection, a clip marker will be placed in the MST for reference. In the ZGT the standard procedure with iodine seeds will be performed for reference. The patient will undergo a pre-operative MRI scan, after injection of Sienna+. The operation will be performed as already planned by the surgeon. In addition to the normal radioactive injection, an additional injection of Sienna+ is administered in the centre of the tumor. During surgery, the sentinel nodes and the tumor will be detected with the normal detector (gamma probe) and the magnetometer (SentiMAG).

Contacts

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Eligibility criteria

Inclusion criteria

1) Patients (male or female) with histologically proven non-palpable breast cancer visible on ultrasound and suitable for SLNB.

2) Patients available for follow-up for at least 12 months

Exclusion criteria

1) Intolerance / hypersensitivity to iron or dextran compounds or Sienna+.

2) Patients who cannot/ do not receive radioisotope for SLNB.

3) Patients with an iron overload disease

4) Patients with pacemakers or other implantable devices in the chest-wall.

Exclusion criteria MRI subprotocol:

1) Metallic splinters in the eye

2) Ferromagnetic haemostatic clips in the central nervous system.

3) Claustrophobia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-07-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44817
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4548
NTR-old	NTR4691
CCMO	NL48593.044.14
OMON	NL-OMON44817

Study results

Summary results
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