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Super Paramagnetic Iron Oxide (SPIO) tracer for sentinel node biopsy (SNB) in breast cancer.

Submission date	Recruitment status	[_] Prospectively registered
19/05/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/05/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2017	Cancer	

Plain English summary of protocol

Background and study aims
The usual method to assess the spread of breast cancer if there are no clinical or radiological signs is to perform a lymph node biopsy in the axilla (armpit). This involves detecting and resecting (removing) the first node that receives lymph from the primary (original) tumour site. This lymph node is called sentinel. The traditional technique to trace it is to use a radioactive marker as well as blue dye, which are injected in the breast and gather in the sentinel node. This is identified visually and by a probe at operation. A new promising technique is the use of magnetic particles that work in the same way; these are super paramagnetic iron oxide nanoparticles (Sienna+). This study wants to test technique as the sole method for the detection of the sentinel node.

Who can participate?
Adults (aged at least 18) about to have a sentinel node biopsy (SNB)at either the Akademiska University Hospital, Uppsala, Sweden or Västmanlands County Hospital, Västerås, Sweden.

What does the study involve?
Patients recruited at Uppsala University Hospital are allocated to the intervention group. They are given a dose of Sienna+ (along with a local anaesthetic) either during their visit to the outpatient clinic before they have their surgery or at least 20 minutes before they have their surgery. Patients recruited at the Västmanlands County Hospital undergo the usual SNB technique. All patietns are followed up to see how effective the treatment is and how feasible it is to inject the Sienna+. Patients in the intervention group are also asked (via a questionnaire) about possible skin staining after the procedure and how much of a problem do they think it is. Finally, a cost-benefit analysis is performed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. Uppsala University Hospital (Sweden)
2. Västmanlands County Hospital (Sweden)

When is the study starting and how long is it expected to run for?
June 2014 to June 2016

Who is funding the study?
Uppsala University (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Ethics Comittee Uppsala University, DNR 2014/073 + 2014/073/1 + 2014/073/2.

Study information

Scientific Title
The routine use of super paramagnetic iron oxide nanoparticles as the sole method for sentinel node biopsy in patients with breast cancer. The MONOS study.

Study objectives
The sole use of SPIO nanoparticles (Sienna+) is as effective as the combination of Tc99 and blue dye in the detection of sentinel nodes in patients with breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee Uppsala University, 29/03/2014 (ref: 2014/073) and 16/12/2015 (ref: 2014/073 /2)

Study design
Prospective open label inteventional trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Patients are recruited from Akademiska University Hospital, Uppsala, Sweden and Västmanlands County Hospital, Västerås, Sweden. Patients recruited at Uppsala University Hospital will be enrolled in the SPIO (Sienna+®) arm, whereas patients at Västmanlands County Hospital in Västerås will be assigned in the control (dual technique) arm.

For the intervention group, SPIO nanoparticles (Sienna+, Sysmex Europe). The dose is 2ml of Sienna+ blended with 3ml of local anaesthetic - Xylocain®, 10mg/ml) and is injected interstitially either during the preoperative visit to the outpatient clinic or about one hour but, at least 20 minutes before the operation. If the transcutaneous signal is deemed inadequate, 1-2 ml of Patent Blue® will be administered interstitially at the areolar border 10 minutes before skin incision.

The control arm consists of patients with with breast cancer with indication for sentinel node biopsy, who will undergo SNB using the standard dual technique, consisting of interstitial injection of 40-60mBq Tc99 the morning before surgery or the day before with the addition of blue dye as above, in standard fashion.

Intervention Type
Device

Primary outcome(s)
1. Intraoperative detection rate per case defined as the number of successful cases per method divided by the total amount of cases performed in the respective arm (Sienna+ and Tc99).
2. Detection rate per case, specific for patients injected with Sienna+ in the preoperative outpatient setting and not perioperatively.
3. Intraoperative detection rate per node defined as the number of nodes retrieved successfully per method divided by the total amount of nodes retrieved in the respective arm (Sienna+ and Tc99).

Key secondary outcome(s))
1. Size and fading of staining (intervention arm only) in the postoperative period (at 3, 6, 9,12,15, 18 months) . The size of staining will be measured in maximum dimensions and the intensity of the staining will be registered as to if it is persistent or paler.
2. Problems experienced by patients due to remaining skin staining, assessed with Likert scale

from 0 (not a cosmetic problem at all) to 5 (very ugly)) at 15 and 18 months postoperative.
3. Costs per method per patient
4. Primary benefit cost analysis

Completion date
10/06/2016

Eligibility

Key inclusion criteria
1. Adults (>18 yrs of age)
2. Mentally capable of processing information.
3. Patients scheduled for a SNB

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with pacemaker or other implantable metallic devices in the chest
2. Patients with allergy or intolerance to iron and dextran compounds
3. Patients with hemochromatosis
4. Pregnant patients
5. Lactating patients

Date of first enrolment
01/09/2014

Date of final enrolment
10/06/2015

Locations

Countries of recruitment
Sweden

Study participating centre

Uppsala University Hospital
Uppsala
Sweden
751 85

Study participating centre
Västmanlands County Hospital
Västerås
Sweden
721 89

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type
University/education

Funder Name
Uppsala Universit

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017		Yes	No