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Postoperative breast MRI in patients undergoing sentinel node biopsy using super paramagnetic iron oxide nanoparticles

Submission date
30/12/2017

Recruitment status
No longer recruiting

Registration date
16/01/2018

Overall study status
Completed

Last Edited
16/01/2018

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Superparamagnetic iron oxide (SPIO) nanoparticles are a new tracer for the detection of breast cancer. Recent results have shown that injection of SPIO up to 4 weeks before surgery is feasible and increases detection rates. This is a very important advantage as it saves time during surgery. However, due to its paramagnetic properties, SPIO causes artefacts on MRI and if MRI has to be performed, it has to be done before the injection of SPIO. Skin staining is the most common side effect of SPIO injection. It has been shown to be related to the prolonged residence of the substance in the tissue, which is shown by the fact that stained tissue has a magnetic signal and that it is almost exclusively observed in breast conserving surgery. This is a matter of interest for patients who need to be followed up with MRI after surgery. The long lasting staining may pose a restriction as MRI will be contaminated by SPIO artefacts. Staining is significantly less if SPIO is injected deeply, near the tumour. The aim of this study is to confirm that, since the injected tissue and most of the SPIO are removed, there should not be any SPIO artefacts, or they should be much smaller.

Who can participate?
Women with breast cancer undergoing breast conserving surgery

What does the study involve?
After surgery, the background magnetic count is recorded. Skin staining and magnetic activity in the breast 2-3 weeks after the operation are recorded and the patients are followed up with an MRI scan 3 months after the operation. Depending on the present of artefacts, MRI follow up may be extended to 5 years after the operation.

What are the possible benefits and risks of participating?
Participants have a more frequent follow-up, but no other form of compensation or benefit. Taking part in the study has no risks for the patients, as breast MRI within the study is conducted without using intravenous paramagnetic contrast. The decision for contrast is made individually according to clinical indications.

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

When is the study starting and how long is it expected to run for?
September 2017 to February 2023

Who is funding the study?
Uppsala University (Sweden)
Endomagnetics Ltd

Who is the main contact?
Dr Andreas Karakatsanis

Contact information

Type(s)
Scientific

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751 85

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The compatibility of POSToperative breast MRI in patients who underwent MAGnetic guided sentinel lymph node biopsy (POSTMAG MRI): a prospective study

Acronym
POSTMAG MRI

Study objectives
Superparamagnetic iron oxide (SPIO) nanoparticles are a novel tracer for the detection of sentinel node (SN) in patients with breast cancer. Apart from comparable performance of SPIO as a sole tracer to the dual standard, recent results have demonstrated that the preoperative injection of SPIO up to 4 weeks preoperatively in an outpatient basis is feasible and leads to enhancement of the detection rates, compared to the perioperative administration. This is a very important advantage, since it simplifies logistics and reduces operative time. However, due to its paramagnetic properties, SPIO causes artefacts on MRI and, if MRI has to be performed, it has to be done before the injection of SPIO.

Skin staining is the most common side effect of SPIO injection. It has been shown to be related to the prolonged residence of the substance in the tissue, a remark that is enhanced by the facts that stained tissue has a magnetic signal and that it is almost exclusively observed in breast conserving surgery (BCS). This is a matter of interest for patients who need to be followed postoperatively with MRI. Despite the fact that the indications are few, the long lasting staining may pose a restriction since MRI will be contaminated by SPIO artefacts. Peritumoral injection yields comparable SN detection rates and is connected with the presence of less staining, since the injected tissue is excised.

This prospective observational study will assess the compatibility of postoperative MRI in patients who have been injected peritumourally with SPIO for SN biopsy.

Hypothesis: Background counts on a magnetometer as well as skin discoloration correlate to the amount of SPIO residual in the tissue after breast conservation and therefore with the presence of artefacts on postoperative MRI in patients who underwent sentinel node biopsy for breast cancer with the use of SPIO.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Uppsala University, 20/07/2017, ref: DNR 2014/073 + 2014/073/1 + 2014/073 /2

Study design
Multicentre observational longitudinal study.

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Women undergoing BCS will take part in the study. After specimen excision, the background magnetic count will be registered. Postoperative skin staining and magnetic activity in the breast 2-3 weeks postoperatively will be registered and the patients will be followed with an MRI 3 months after the operation. Depending on the presence of artefacts, MRI follow-up may be extended to 5 years postoperatively.

Intervention Type
Other

Primary outcome measure
Magnetic signal in the breast and discoloration are registered intraoperatively, 1 and 3 months after surgery. If SPIO artefacts are seen on postoperative baseline MRI conducted 3 months after the operation, the patient will be followed up 6 months postoperatively and thereafter annually with controls as stated above up to 5 years postoperatively

Secondary outcome measures
Impact of different SPIO volumes on the prevalence of skin staining and MRI artefacts

Overall study start date
01/09/2017

Completion date
01/02/2023

Eligibility

Key inclusion criteria
Patients with DCIS or T1 to T3 invasive breast cancer planned for BCS and SNB study

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
A minimum of 93

Key exclusion criteria

1. Intolerance/hypersensitivity to iron or dextran compounds or Sienna XP
2. Patients with an iron overload disease
3. Patients with pacemakers or other implantable devices in the chest-wall, or prosthesis in the shoulder
4. Patient deprived of liberty or under guardianship
5. Pregnant or lactating patients
6. Intraoperative or postoperative conversion to mastectomy
7. Inability to provide informed consent

Date of first enrolment
01/09/2017

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University Hospital
751 85

Study participating centre
Västmanland County Hospital
721 89

Sponsor information

Organisation
Uppsala University

Sponsor details
Uppsala University
Uppsala
Sweden
751 05

Sponsor type
University/education

Website
uu.se

ROR
https://ror.org/048a87296

Funder(s)

Funder type
University/education

Funder Name
Uppsala Universitet

Alternative Name(s)
Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
Endomagnetics Ltd

Results and Publications

Publication and dissemination plan
The study protocol will be made available upon request to the investigators. Results are expected to be announced and published in a high-impact peer reviewed journal within a year after the completion of follow-up.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date