ISRCTN11914537 https://doi.org/10.1186/ISRCTN11914537

MAGnetic marker TO detect primary lesion and sentinel node in breast cancer. The randomised MAGTOtal trial.

Submission date	Recruitment status	[_] Prospectively registered
27/03/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/05/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/12/2023	Cancer	

Plain English summary of protocol

Current plain English summary as of 19/10/2018:
Background and study aims
The study aims to compare a new technique of tumour marking in patients with breast cancer.

Who can participate?
Adult women with non-palpable breast cancer (cancer that cannot be felt using the fingers) suitable for
breast-conserving surgery.

What does the study involve?
Study participants will be randomised to the marking of the breast tumour with either a guide wire (a thin wire placed into the tumor using a mammogram or ultrasound) or a magnetic clip that will serve as a guide for tumour removal with guidance during the operation from a hand-held magnetism detector.

What are the possible benefits and risks of participating?
Patients participating in the study will undergo a closer follow-up in the postoperative period. No financial reimbursement will be provided. The risks are the same as for a simple breast tissue biopsy and include pain, swelling and bruising.

Where is the study run from?
The study is run from the Breast Unit of Uppsala University Hospital, which is the lead centre. The trial will be undertaken in Uppsala University Hospital and in Västmanlands County Hospital.

When is the study starting and how long is it expected to run for?
October 2017 to February 2022 (updated 05/11/2019, previously: December 2019)

Who is funding the study?
The study is funded by Uppsala University. The magnetic markers (Magseed) and the tracer for the sentinel node biopsy (SiennaXP) will be provided by EndoMagnetics (Cambridge, UK).

Who is the main contact
Main contact for the study is Andreas Karakatsanis, MD, PhD, FEBS, Consultant Oncoplastic Surgeon, Uppsala University Hospital.

Previous plain English summary
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When is the study starting and how long is it expected to run for?
The study is expected to start recruiting by May 1st, 2018. Patient recruited is expected to be completed by October 2018.

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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MagTotal

Study information

Scientific Title
Tumour localization and sentinel lymph node identification using a magnetic localisation marker (Magseed) and super paramagnetic iron oxide nanoparticles (SiennaXP): The randomised MagTotal trial

Acronym
MagTotal

Study objectives
The MagSeed tracer is non-inferior to the guidewire in successful resection of the primary tumour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uppsala Regional Ethics Commitee, 10/01/2018, DNR 2017/508

Study design
Open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Patients partaking in the study will be allocated to marking of the tumour either with Magseed or a guidewire. Allocation will be performed with block randomisation using a block size of 10 and an allocation ratio of 1:1 using a random number generator software . The SPIO Sienna XP© will be injected in the preoperative period, peritumorally by the breast radiologist guided by ultrasound or mammography in non-palpable lesions. At the same time, the breast radiologist will insert the Magseed close to the tumour in patients allocated in the Magseed arm. In patients randomised to tumour localization by guide wire, the guide wire will be inserted on the same day as the surgery.

During breast-conserving surgery (BCS) the transcutaneous signal by SentiMag in the breast and axilla, as well as the presence and size of skin staining will be registered. After the excision of the primary tumour, a specimen count as well as a background count will be performed.
In the post-operative visit to the outpatient clinic, staining and magnetic signal in the breast will be registered. At the postoperative multidisciplinary team meeting the need of a reoperation due to non-radical resection will be registered. The number of sentinel nodes (SNs) and non-SNs and the occurrence of lymph node metastases will be registered.

Intervention Type
Procedure/Surgery

Primary outcome measure
Radical excision, defined as free surgical margins of the specimen of the primary tumour according to preoperative diagnosis.

Secondary outcome measures
1. Width of margins per study arm in mm from the tumour to the resection margin both on specimen radiology and on final pathology.
2. Operative time from the beginning of the breast operation until the excision of the specimen in minutes.
3. Intraoperative and postoperative complications on 30 days, described by the Clavien Dindo classification and the Comprehensive Complication Index (CCI) (www.assessurgery.com).
4. Cost/benefit analysis based on the expenses of inpatient and outpatient care regarding the operation and 30 days of the postoperative period.

Overall study start date
24/10/2017

Completion date
01/02/2022

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Ductal carcinoma in situ (DCIS) or invasive breast cancer requiring localisation planned for primary surgery including sentinel node biopsy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Total final enrolment
426

Key exclusion criteria
1. Intolerance or hypersensitivity to iron or dextran compounds or Sienna XP
2. Iron overload disease
3. Pacemaker or other implantable device in the chest-wall, or prosthesis in the shoulder
4. Deprived of liberty or under guardianship
5. Pregnant or lactating
6. Inability to provide informed consent

Date of first enrolment
01/04/2018

Date of final enrolment
30/10/2021

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

Sponsor details
Uppsala University
Uppsala
Sweden
751 05

Sponsor type
University/education

Website
uu.se

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Not defined

Funder Name
Endomagnetics, Cambridge, UK

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Andreas Karakatsanis (andreas.karakatsanis@surgsci.uu.se) and Fredrik Wärnberg (fredrik.warnberg@surgsci.uu.se) after all results have been originally published. Anonymised patient level data after appropriate patient consent will be made available for scientific and academic purposes, i.e. for the conduct of pooled analyses or patient level meta-analyses. Study data will be kept for 20 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/12/2023	28/12/2023	Yes	No