ISRCTN11807786 https://doi.org/10.1186/ISRCTN11807786

Comparing the cost-effectiveness of two commonly used types of dye for determining whether cancer has spread into the lymphatic system

Submission date 13/04/2022	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol
Registration date 08/12/2022	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 14/12/2023	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English Summary

Background and study aims
Women with a small breast cancer require surgery to remove the cancer from their breast and also to remove a few lymph nodes from their armpit (sentinel node biopsy) at the same time to see whether the cancer has spread. These women have an injection of a dye before their surgery which demonstrates the lymph nodes the surgeon needs to remove. This study aims to compare the cost-effectiveness of two commonly used types of dye for sentinel node biopsy - Magtrace and technetium.

Who can participate?
Women aged 18 years or above with breast cancer

What does the study involve?
Participants will be randomly allocated to have either Magtrace or technetium. A research assistant will shadow these women in their visits to the hospital before surgery and work out the hospital costs associated with each treatment.

What are the possible benefits and risks of participating?
The potential benefits of using Magtrace® will be in simplifying the patient pathway before surgery. Magtrace® will be given on the day of surgery, whereas technetium would be given on the day of surgery or the day before. This means around the time of surgery there will be less stress for the patient, they will be ready to have their surgery at any time of the day (rather than having to wait until they have a technetium injection). Technetium requires aliquoting out from the Christie and transporting across to the nuclear medicine department on a daily basis, and following radioactive licences, must be given by two trained professionals in a very controlled manner. Magtrace® can be given by any trained member of staff without the need for radioactivity licences. It will negate the need for the complex process of transferring the nuclear medicine across the city and the need for staff to make up the injections every morning and give them to patients. Magtrace® will therefore simplify the pathway and remove multiple steps

freeing up staff for other jobs. Magtrace® will make theatre scheduling in the morning easier as any patient will be available for theatre, potentially making less waiting for theatre staff and more efficient operating. It is unlikely that extra cases will be done as a result of the change but it may avoid overruns and delays in theatre.
All processes and technologies have previously been proven to be effective. Technetium sentinel node injection is often combined with a blue dye. The blue dye has a small risk of anaphylaxis (a severe, potentially life-threatening allergic reaction) of about 1 in 10,000 and can stain the skin of the breast blue for several months. Magtrace® does not have a risk of anaphylaxis but can stain the skin of the breast brown for several months post-operatively.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2020 to May 2025

Who is funding the study?
Endomag (UK)

Who is the main contact?
Mr James Harvey, james.harvey@mft.nhs.uk

Contact information

Type(s)
Principal Investigator

Contact name
Mr James Harvey

ORCID ID
http://orcid.org/0000-0002-1359-2186

Contact details
Nightingale Centre
Manchester University NHS Foundation Trust
Southmoor Road
Manchester
United Kingdom
SK23 7EJ
+44 (0)1612914436
james.harvey@mft.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293053

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 293053, CPMS 53234

Study information

Scientific Title
Magtech: cost-effectiveness and benefits of Magtrace® versus Technetium in sentinel node biopsy for breast cancer

Acronym
Magtech

Study hypothesis
Single-site case-control study investigating the healthcare costs of Magtrace®, and a discrete-choice qualitative experiment of the perceived value of Magtrace® vs the current standard of care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2022, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048009; gmeast.rec@hra.nhs.uk), ref: 22/NW/0192

Study design
Single-site case-control study and a discrete-choice qualitative experiment

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 to request a participant information sheet

Condition
Early breast cancer

Interventions
Using a stopwatch, research staff have the ability to consent and then actively monitor (shadow around the hospital) a group of ~20 patients in each treatment group (Magtrace® vs routine care using Technetium nuclear medicine). It is critical prior to recruitment that key covariates and factors likely to influence not only outcomes but also health economic factors of care are identified. These factors will require consideration before randomisation to Magtrace or routine care, with randomisation recommended to take place using sealed envelopes in blocks of ten. If imbalances in key covariates occur following randomisation, adjustment of health economic outcomes will be performed to mitigate these imbalances using gold-standard two-stage bootstrapping for cost-effectiveness analyses.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Magtrace®, technetium

Primary outcome measure
Cost-effectiveness of Magtrace® compared to Technetium in the identification of sentinel nodes in breast cancer, measured using data records over duration of the study.

Secondary outcome measures
1. Patient time spent in hospital and in transit in total over the preoperative and perioperative journey, measured using electronic patient records over the duration of the patient visit.
2. Patient anxiety on the day of surgery measured using the State-Trait Anxiety Inventory (STAI-Y) given on the ward on the morning of surgery
3. Number and length of patient hospital visits comparing preoperative visits (clinic visits, preoperative assessment, tracer injection visits, ward visits and operative visits), measured on the day of surgery
4. Safety of Magtrace® and efficacy: adverse events relatable to tracers, number of nodes removed, number of nodes containing tracer, % of patients with detectable tracer in the axillary sentinel nodes, can surgeons differentiate Magtrace® and Magseed signal®, recorded for as long as the participant is on the trial
5. Cost per episode and for total care, measured using activity-based costing (TDABC). TDABC is a bottom-up approach to healthcare pathway mapping and costing, which records pathways observed during routine clinical practice, identifies all points and durations of interaction with healthcare providers therein; and assigns time-dependent costs to each constituent.
6. Surgical start time, days of week of operating, and delays to getting patients to the theatre. Delays will be recorded by asking the theatre team directly pre-operatively whether they had to wait for the patient to arrive and what the reason was, and also whether the list had to be rescheduled/moved to accommodate a delay, measured using electronic patient records over the duration of the patient visit.
7. Current pathways of patient care: the research assistants provide a ‘learned’ assessment of what they believe represents a ‘typical’ pathway at the Nightingale centre. A multidisciplinary team will then assess the validity of this pathway and voice any concerns/objections/potential additions. The duration of each patient visit is monitored throughout the trial.
8. Key aspects of care pathways important to patients and healthcare professionals in the management of breast cancer; in order to ensure that all relevant points of interaction with

healthcare staff, and utilisation of health services, are captured, the pathway will be amended as necessary. Duration of the patient visit.
9. Preferences/overall satisfaction with the care package for Magtrace vs Technetium from the perspective of patients and healthcare providers. Once data is collected for 20 patients undergoing Magtrace, and 20 patients undergoing routine care, it will be possible to multiply NHS resource utilisation by representative NHS unit costs (staff salaries per minute, radiography, inpatient, nuclear medicine) and determine an array of health economic outcomes. The result will be a health-economic comparison of Magtrace® over Technetium nuclear medicine. Sensitivity analyses will be performed on this dataset to measure the robustness of the findings to changes in the values of the parameters measured during the TDABC stopwatch exercise. Rather than relying on point estimates, this will enable the derivation of credible intervals, and determine how specific factors such as time in the hospital, number of visits, requirements for isotopes etc.

Overall study start date
07/10/2020

Overall study end date
01/05/2025

Eligibility

Participant inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Female aged 18 years or above
3. Diagnosed with breast cancer (invasive) requiring Magseed® localisation and sentinel node biopsy
4. Willing to allow her General Practitioner and consultant, if appropriate, to be notified of participation in the study
5. Undergoing breast-conserving surgery with sentinel node biopsy
6. Surgeons may only operate on the Magtrace arm of the study if they have completed a minimum of five training cases with Magtrace

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50

Participant exclusion criteria

1. Patients with a pacemaker or implanted device in the chest wall
2. Patients who are pregnant or lactating
3. Patients who have received Magtrace® (iron oxide) injection in the previous 6 months
4. Patients with previous ipsilateral axillary surgery
5. Patients whose breast and axillary surgery are not due to be performed synchronously
6. Patients following neoadjuvant chemotherapy
7. Patients who require MRI follow-up of the ipsilateral breast in the year following surgery (as Magtrace® may interfere with MRI)
8. Patients requiring an interpreter
9. Patients involved in current research or have recently been involved in any research prior to recruitment

Recruitment start date
01/05/2024

Recruitment end date
01/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Southmoor Road
Manchester
England
United Kingdom

M23 9LT
+44 (0)1612914436
charlotte.bryant@mft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://mft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Endomag

Results and Publications

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

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	03/08/2022	24/10/2022	No	No
HRA research summary			26/07/2023	No	No