

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

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<b>Registration date</b> 08/12/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/12/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

293053

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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 objectives

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

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

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(s)**

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.

## **Key secondary outcome(s)**

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.

**Completion date**

01/05/2025

## Eligibility

**Key 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Key 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

**Date of first enrolment**

01/05/2024

**Date of final enrolment**

01/05/2025

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Wythenshawe Hospital**

Southmoor Road

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M23 9LT

## Sponsor information

**Organisation**

Manchester University NHS Foundation Trust

**ROR**

<https://ror.org/00he80998>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Endomag

## Results and Publications

**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?
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1	03/08/2022	24/10/2022	No	No