

The MOLL trial - Magnetic lesion localisation for breast cancer

Submission date 31/08/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/01/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-a-new-way-to-find-and-remove-breast-cancer-moll-trial>

Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number

35018

Study information

Scientific Title

Magnetic Occult Lesion Localization for the surgical management of non-palpable Breast Cancer: The MOLL trial

Acronym

MOLL trial

Study objectives

The aim of this study is to determine the feasibility of using the Tokyo magnetometer and a magnetic marker for wide localized excision in breast cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North East - York Research Ethics Committee, 04/07/2017, ref: 17/NE/0195

Study design

Non-randomised; Interventional; Design type: Treatment, Device, Imaging, Surgery

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Cancer, Primary sub-specialty: Breast Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasm of breast

Interventions

There is no randomisation or separate treatment arms, as all participants included in the study follow the same procedure.

On the morning prior to surgery the participant receives an injection with a magnetic marker which is placed into the centre of the non-palpable breast tumour. This is done instead of the standard procedure of inserting a wire used to localise breast tumours as it is no longer required. This procedure takes approximately 15 minutes (identification of the tumour, insertion of the marker and identification of the marker into the tumour).

Participants undergo the wide local excision (WLE) surgery. The surgeon uses a hand-held magnetometer to detect the shortened wire (magnetic marker) and excise the whole tumour. This takes approximately 5 minutes (includes multiple detections during surgery). The surgery is undertaken as usual and the standard x-ray of the excised tissue is also performed as standard.

Participants are followed-up for one year, which is standard protocol. Participants are assessed to see if the magnetic marker and excision of the breast tumour is successful during surgery. Re-excision rates, cosmetic outcomes and morbidity are assessed post operatively.

Intervention Type

Other

Primary outcome(s)

Successful localization of a magnetic marker and excision of the breast tumour is assessed using a magnetic marker and magnetometer during surgery.

Key secondary outcome(s)

1. Re-excision rate is assessed by reviewing patient notes post-operatively
2. Excised specimen volumes are assessed by weighting the excised tissue volumes during surgery
3. Cosmetic outcome is assessed by reviewing patient notes post-operatively after 3 months and at 1 year follow-up
4. Morbidity from WLE is assessed by reviewing patient notes post-operatively

Completion date

01/04/2019

Eligibility

Key inclusion criteria

1. Males/females (18 years or over)
2. A non-palpable breast tumour
3. Visible on ultrasound
4. Suitable for wire guided lesion localisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Known intolerance / hypersensitivity to iron compounds
2. Patients with a pacemaker or other implantable devices in the chest wall

Date of first enrolment

21/09/2017

Date of final enrolment

01/04/2018

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**Guy's Hospital**

Research Oncology

Third floor Bermondsey Wing

Great Maze Pond

London

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SE1 9RT

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Government

Funder Name

Association of Breast Surgery

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No