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The MOLL trial - Magnetic lesion localisation for breast cancer

Submission date	Recruitment status	[X] Prospectively registered
31/08/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/09/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/01/2018	Cancer	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

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

Secondary outcome measures
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

Overall study start date
01/04/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

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
England

United Kingdom

Study participating centre
Guy's Hospital
Research Oncology
Third floor Bermondsey Wing
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
Trust Offices
Guy's Hospital
Great Maze Pond
London

England
United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Association of Breast Surgery

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Additional information such as the protocol is available on request.

Intention to publish date
01/04/2019

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