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Magnetic Sentinel Node and Occult Lesion Localisation (MagSNOLL)

Submission date	Recruitment status	[_] Prospectively registered
10/09/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/03/2017	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-way-of-finding-very-small-breast-cancers-and-sentinel-lymph-nodes-magnoll

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14979

Study information

Scientific Title
Magnetic Sentinel Node and Occult Lesion Localisation: A feasibility study using magnetic nanoparticles for sentinel node biopsy and localisation of occult breast cancers

Acronym
MagSNOLL

Study objectives
In the UK, breast cancer is the most common cancer in women with over 50,000 newly diagnosed patients in 2010. The implementation of breast screening programmes and diagnostic improvements have resulted in up to 35 percent of breast cancers being clinically nonpalpable on diagnosis. The current gold standard for the treatment of these occult lesions is excision by wire guided localisation (WGL). However, WGL has drawbacks. Alternatives have been introduced, but these rely on radioactive materials which have cost and waste management disadvantages. We have developed a handheld magnetometer (SentiMag, Endomagnetics UK) capable of detecting a magnetic dye (Sienna +, Endomagnetics UK) injected into the breast. This technology has already been successfully applied to sentinel lymph node biopsy (SLNB) and is the subject of an NIHR-adopted, UK multicentre trial (SentiMAG Multicentre Trial; Chief Investigator Michael Douek) in breast cancer. We would like to evaluate the use of the same magnetic dye (Sienna+) for both localisation of nonpalpable breast lesions and concurrent SLNB using the SentiMag handheld magnetometer.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14979

Ethics approval required
Old ethics approval format

Ethics approval(s)
City Road and Hampstead, 17/06/2013, ref: 13/LO/0636

Study design
Non-randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
Injection of magnetic dye, Intra-tumoral injection of 0.5 mL magnetic dye (Sienna+)

Follow Up Length: 12 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Successful sentinel lymph node biopsy and lesion localisation.

Key secondary outcome(s))
No secondary outcome measures

Completion date
06/08/2014

Eligibility

Key inclusion criteria
1. Patients with operable breast cancer visible on ultrasound and suitable for SLNB 2. Neoadjuvant chemotherapy sub-protocol:
Patients with breast cancer due to undergo neoadjuvant chemotherapy and post-chemotherapy SLNB
3. Target Gender: Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Intolerance / hypersensitivity to iron or dextran compounds or Sienna +
2. Patients who cannot / do not receive radioisotope for SLNB
3. Patients with an iron overload disease
4. Patients with pacemakers or other implantable devices in the chestwall

Date of first enrolment
07/08/2013

Date of final enrolment
06/08/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bermondsey Wing
London
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SE1 9RT

Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Endomagnetics Limited (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2015		Yes	No
HRA research summary			28/06/2023	No	No