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A feasibility study comparing the safety and acceptability of vacuum-assisted biopsy and conventional 14-gauge core biopsy in the diagnosis of ultrasonically indeterminate and abnormal axillary lymph nodes

Submission date
12/06/2014

Recruitment status
No longer recruiting

Registration date
12/06/2014

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-two-ways-taking-samples-tissue-lymph-nodes-under-arm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14676

Study information

Scientific Title
A feasibility study comparing the safety and acceptability of vacuum-assisted biopsy and conventional 14-gauge core biopsy in the diagnosis of ultrasonically indeterminate and abnormal axillary lymph nodes

Study objectives
Women with invasive breast cancer undergo ultrasound of the axilla (armpit) before surgery to detect spread of disease (metastases) to the lymph nodes. If this is normal the woman undergoes operative sentinel lymph node biopsy (SLNB), usually at the same time as surgery to the breast. If the SLNB is positive the woman undergoes axillary node clearance at a subsequent operation.

Abnormal axillary lymph nodes on ultrasound undergo needle sampling. If metastases are confirmed the woman undergoes node clearance at the same operation as surgery to the breast. The number of women who need to undergo more than one operation can be minimised by maximising the number of women with axillary metastatic disease who are diagnosed before surgery.

Ultrasound has a sensitivity of ~60% for the detection of metastatic lymph nodes. Ultrasound-guided biopsy of nodes that contain metastases has a sensitivity of ~80%. This is less than 100% because the needle may miss the part of the lymph node containing the tumour deposit. Increasing the volume of tissue removed may increase accuracy.

Vacuum-assisted biopsy (VAB) is a needle technique performed under local anaesthetic which allows more tissue to be removed than with a standard needle. Repeated samples can be taken with a single needle insertion, allowing large numbers of samples to be quickly taken. VAB of breast abnormalities is well tolerated by patients.

This study will determine whether the use of VAB in the axilla is safe and acceptable to patients and whether a larger randomised study comparing the two techniques is feasible. The results will inform the design of a larger study which will determine whether VAB significantly increases the preoperative diagnosis rate of axillary metastatic disease. If it does, its use will result in a reduction in the number of second operations in women with breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/NW/0326

Study design
Randomised controlled trial

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 patient information sheet

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

Interventions
Participants randomised to have axillary lymph node biopsy with either 14-gauge core needle biopsy device or a 13-gauge or 10-gauge vacuum biopsy device.

Study Entry : Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of women who would be willing to undergo the biopsy again.; Timepoint(s): 4 to 14 days post-biopsy

Secondary outcome measures
1. Procedure pain scores; Timepoint(s): Immediate and at 4-14 days post-biopsy
2. Proportion of women approached who are willing to enter the study.; Timepoint(s): AT recruitment
3. The sensitivity of vacuum biopsy relative to conventional core biopsy (preliminary data only); Timepoint(s): Following surgery

Overall study start date
20/06/2013

Completion date
17/06/2014

Eligibility

Key inclusion criteria
1. Women in screening and symptomatic clinics aged >35 years with breast masses scored as:
1.1. M4 or M5 (mammographically suspicious or highly suspicious of malignancy) and U5 (ultrasonically highly suspicious of malignancy)
1.2. and/or MRI5 (highly suspicious of malignancy on MRI) and U5
1.3. and/or have histologically proven breast cancer
1.4. and who have ultrasonically indeterminate or abnormal ipsilateral axillary lymph nodes (i.e. suspicious of metastatic disease)
2. Indeterminate / abnormal lymph nodes are defined as those with >2.3mm lymphoid thickness and/or focal cortical bulging and/or non-hilar blood flow and/or loss or reduction in the normal hilar fat

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
80

Key exclusion criteria
1. Women who are on anticoagulants or have known clotting disorders
2. Previous ipsilateral axillary surgery
3. Target lymph node not suitable for vacuum biopsy due to its proximity to critical structures such as major blood vessels

Date of first enrolment
20/06/2013

Date of final enrolment
17/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University of Manchester
Manchester
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Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust (UK)

Sponsor details
Wythenshawe Hospital, Southmoor Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
British Society of Breast Radiology (BSBR) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/06/2016	11/07/2019	Yes	No
Plain English results			26/10/2022	No	Yes
HRA research summary			28/06/2023	No	No