# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
12/06/2014		Protocol		
Registration date 12/06/2014	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
26/10/2022	Cancer			

### 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

### Contact name

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### Contact details

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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 United Kingdom M23 9LT

# Sponsor information

### Organisation

University Hospital of South Manchester NHS Foundation Trust (UK)

### Sponsor details

Wythenshawe Hospital, Southmoor Road Wythenshawe Manchester England United Kingdom M23 9LT

### 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	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2016	11/07/2019	Yes	No
Plain English results			26/10/2022	No	Yes
HRA research summary			28/06/2023	No	No