Multifrequency bioimpedance in the early detection of lymphoedema

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/10/2010		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/08/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
13/03/2020	Cancer			

Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-new-way-of-detecting-early-signs-of-lymphoedema-after-breast-cancer-surgery

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

8881

Study information

Scientific Title

Multifrequency bioimpedance in the early detection of lymphoedema after axillary surgery: an observational cohort study

Study objectives

The purpose of this multicentre study is to test whether there is concordance between bioimpedance and perometer arm measurements and in particular, whether bioimpedance identifies patients who are developing lymphoedema at an earlier stage, before arm volume measurement by perometry shows significant increases in arm volume.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Birmingham Research Ethics Committee, 19/03/2010, ref: 10/H1207/22

Study design

Observational multicentre cohort study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Lymphoedema in patients with breast cancer

Interventions

Arm volume will be measured at baseline, 1, 3, and 6 monthly thereafter to 2 years, followed by annual measurements up to 5 years using perometer arm scanning and bioimpedance. Quality of Life questionnaires (FACT B+4 and EQ5D) and a lymphoedema questionnaire will be administered as baseline, 3, 6, 12, 18, 24, 36, 48 and 60 months.

Follow up length: 60 months Study entry: registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Incidence of lymphoedema (greater than 10% arm volume increase compared to contralateral arm) at 2 and 5 years

Key secondary outcome(s))

- 1. Comparison of multi-frequency bioimpedance with perometer measurement
- 2. Prediction of lymphoedema by multi-frequency bioimpedance at 24 months
- 3. Quality of life in each group
- 4. Multivariate model assessment of factors predicting lymphoedema at 24 months
- 5. Lymphoedema symptoms related to changes in arm volume and bioimpedance readings

Completion date

29/07/2015

Eligibility

Key inclusion criteria

- 1. Women aged 18 90 years
- 2. Early breast cancer (no evidence of metastatic disease by local screening procedures) scheduled to undergo axillary node clearance
- 3. Willing to consent to pre-surgical arm measurements by perometry and beauvericin (BEA)
- 4. Agreeable to follow-up for up to 5 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. Any patients unwilling to consent to pre-surgical baseline measurements
- 2. Known distant metastasis
- 3. Inoperable breast cancer (T4 category or distant metastasis)
- 4. Node negative not undergoing axillary clearance
- 5. Previous axillary radiotherapy or clearance
- 6. Past history of breast / chest wall radiotherapy
- 7. Previous axillary clearance; either uni- or bi-lateral
- 8. Pregnancy
- 9. External pacemaker / defibrillator

Date of first enrolment

29/07/2010

Date of final enrolment

29/07/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre South Manchester University Hospital

Manchester United Kingdom M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester (UK)

ROR

https://ror.org/00he80998

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created Date add	ed Peer reviewed	? Patient-facing?
Results article	results	01/05/2015	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/20	25 No	Yes