

Multifrequency bioimpedance in the early detection of lymphoedema

Submission date 08/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

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

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 measure

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

Secondary outcome measures

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

Overall study start date

29/07/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 1100; UK sample size: 1100

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

England

United Kingdom

Study participating centre

South Manchester University Hospital

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester (UK)

Sponsor details

Research and Development

Ground Floor ERC

Wythenshawe Hospital

Southmoor Road

Manchester

England

United Kingdom

M23 9LT

Sponsor type

Hospital/treatment centre

Website

<http://www.uhsm.nhs.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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