ISRCTN48880939 https://doi.org/10.1186/ISRCTN48880939

Multifrequency bioimpedance in the early detection of lymphoedema

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

Contact details
South Manchester University Hospital
Nightingale Centre and Genesis Prevention Centre
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT

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