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An investigation into the pathophysiology of breast cancer-related lymphoedema

Submission date 28/11/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/01/2014	**Overall study status** Completed	
Last Edited 27/11/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-understand-more-about-breast-cancer-related-lymphoedema

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/H0701/112 (Protocol no. 8)

Study information

Scientific Title
An investigation into the pathophysiology of Breast Cancer-Related Lymphoedema: a prospective non-randomised study

Acronym
BCRL

Study objectives
To investigate the pathophysiology of BCRL of the arm, concentrating on the following questions:
1. Are some breast cancer patients more likely than others to develop BCRL following their cancer treatment, irrespective of treatment received?
2. What are the factors that contribute to this phenomenon?
3. Is the lymphatic drainage from the arms of breast cancer patients who develop lymphoedema greater than in breast cancer patients who do not develop lymphoedema?
4. Is the production of tissue fluid in the arms of breast cancer patients who later develop lymphoedema greater than in breast cancer patients who do not develop lymphoedema?
5. Is the strength of contraction of the lymphatic vessels in the arms of breast cancer patients who later develop lymphoedema weaker than in breast patients who do not develop lymphoedema?
6. Do communications exist between lymphatic vessels and veins (lymphovenous communications) in the arms to protect some breast cancer patients against lymphoedema?
7. Is the pressure raised in the veins in the arm on the side of the cancer treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC: 09/H0701/112

Study design
Prospective multi-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Breast cancer, lymphoedema

Interventions
For each of the component studies (below), the participant will be asked to attend on two principal occasions lasting no more than half a day each, and to make further shorter visits to the hospital (these take 1520 minutes each).

Study 1 GSTT, Brighton & Sussex Trust and St Georges, University of London - will measure muscle lymph drainage simultaneously in both arms with quantitative lymphoscintigraphy - measured pre-operatively and post-operatively, as soon as the patient is well enough to re-attend.

Study 2 St Georges University London; will measure capillary filtration in both arms using venous occlusion plethysmography; measured pre-operatively and post-operatively, as soon as the patient is well enough to re-attend.

Study 3 St Georges University London; will measure lymphatic pump function on the arm on the same side as the affected breast, using a technique called lymphatic congestion lymphoscintigraphy; measured pre-operatively and post-operatively, as soon as the patient is well enough to re-attend.

Study 4 Brighton & Sussex Trust and GSTT - will investigate lymphovenous communications on the arm of the affected side; patients own RBCs radio-labelled and injected back into patient; blood samples taken from both arms to assess radioactivity; measured pre-operatively and post-operatively, as soon as the patient is well enough to re-attend.

The patients undergoing Studies 14 will be asked to return for additional visits, lasting 1520 minutes each, during which the arms are examined for signs of oedema and their size measured using the perometer or tape-measure (as performed on the two principal visits, described below). These visits will take place following the second principal visit, and will include a key assessment approximately 3 years after the surgery. Relevant findings will be communicated to the lymphoedema clinic.

Study 4a GSTT; will investigate lymphovenous communications on the arm of the affected side in women with and without breast cancer-related lymphoedema; patients own RBCs are radio-labelled and injected back into the patient; blood samples taken from both arms to assess radioactivity; investigation performed once only on patients who are at least 36 months post surgery.

Venous function will be assessed for all patients at all three sites. This is done pre-op only, except in Study 4 (also at post-op and 36 months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Cannot be stated in numerical terms. The principal measurements are as follows:
1. Muscle lymph drainage
2. Capillary filtration rate
3. Lymphatic pump function
4. First appearance of and level of radioactivity in venous blood (as an indication of the presence and concentration of red blood cells)

The patients will be studied pre-operatively and post-operatively (2-4 weeks after their operation) and they will then be followed up annually for clinical examination of the arms for 3 years after their operation.

Secondary outcome measures
Venous pressure: this will be no higher on the side of the cancer treatment than in the opposite arm. The patients will be studied pre-operatively and post-operatively (2-4 weeks after their operation) and they will then be followed up annually for clinical examination of the arms for 3 years after their operation.

Overall study start date
04/08/2010

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Recent diagnosis of breast cancer
2. Surgery or radiotherapy not commenced
3. Scheduled for axillary node excision
4. No other medical condition which will interfere with research procedures
5. Age range 1877 years
6. (4a only) History of breast cancer, at least 3 years post breast cancer surgery, with lymphoedema of the arm on the side of the cancer treatment
7. (4a only) History of breast cancer, at least 3 years post breast cancer surgery, with no lymphoedema of the arm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
240

Key exclusion criteria
1. Previous axillary surgery
2. Previous diagnosis of breast cancer, excepting ductal carcinoma in situ
3. Prior history of lymphoedema
4. Cardiovascular disease (excluding patients with simple hypertension)

1-3 does not apply to patients attending for Study 4a

Date of first enrolment
04/08/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's, University of London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's Healthcare NHS Trust (UK)

Sponsor details
St George's Research Office
Ground Floor
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Sponsor type
Hospital/treatment centre

Website
https://www.stgeorges.nhs.uk/

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015	26/11/2019	Yes	No
Results article	results	01/03/2015	26/11/2019	Yes	No

Results article	results	01/04/2015	26/11/2019	Yes	No
Results article	results	01/06/2016	26/11/2019	Yes	No