# An investigation into the pathophysiology of breast cancer-related lymphoedema

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

#### Contact name

Prof Peter Mortimer

#### Contact details

Clinical Sciences
St George's, University of London
Cranmer Terrace
London
United Kingdom
SW17 ORE

## Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Other

#### 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 reattend.

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(s)

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.

#### Key secondary outcome(s))

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.

#### Completion date

## **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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Female

#### 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

**United Kingdom** 

England

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

## Sponsor information

#### Organisation

St George's Healthcare NHS Trust (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, Cancer Research UK (CRUK), CRUK

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

## **Results and Publications**

#### 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes