

# Evaluation of the upper limb lymphatic system

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>01/03/2016   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>11/03/2016 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>11/03/2016       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The lymphatic system is made up of a network of thin tubes called lymph vessels and lymph nodes. It is a key part of the body's immune system, playing an important role in fighting infections and destroying old or abnormal cells (for example, cancer cells). Lymph nodes are found under the armpits, in the groin and also the neck. Breast cancer often spreads to other parts of the body through the lymphatic system, with cancer cells moving out from the tumour in the breast and into the surrounding lymph nodes. This can cause long term damage to the affected lymph node, stopping it from being able to drain properly. The resulting accumulation of fluid (lymph fluid) results in swelling, often of the arm. Knowledge of the upper limb lymphatic system is mainly based on lymphoscintigraphic studies (that is, studies using a imaging technique to look at the lymph nodes and see how well they are draining) performed in patients with breast cancer-related lymphedema (BCRL). While these studies provide information on the how the disease is affecting the body (pathophysiology) in BCRL, they cannot be used in studies interested in the normal functioning of the lymphatic system. The aim of this study is to evaluate, through lymphoscintigraphy, the function of lymphatics in individuals with an intact (normally functioning) lymphatic system.

### Who can participate?

Patients suffering from melanoma (a type of skin cancer) and healthy volunteers.

### What does the study involve?

Once informed consent has been given by the participants, they undergo a lymphoscintigraphy, which is a scan involving the injection of a small quantity of a radioactive substance called technetium-99m nanocolloid. The injection is made into the skin of the second webspace of each hand (the flashy area between thumb and forefinger) . Patients then lie down so that a gamma camera can be used to take pictures of the upper limbs. This data is then used to look at the functioning of their lymphatic system.

### What are the possible benefits and risks of participating?

Patients are exposed to radiation, but at a dose very likely to place them at risk.

### Where is the study run from?

University Hospital "P. Giaccone", Department of Surgical, Oncological and Oral Sciences, University of Palermo (Italy)

When is the study starting and how long is it expected to run for?  
April 2013 to February 2016

Who is funding the study?  
University of Palermo (Italy)

Who is the main contact?  
Dr. Matteo Rossi  
matt.rossi17@virgilio.it

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Matteo Rossi

**ORCID ID**  
<https://orcid.org/0000-0002-5265-8299>

**Contact details**  
University of Palermo  
Department of Surgical, Oncological and Oral Sciences  
Plastic and Reconstructive Surgery  
Via del Vespro, 129  
Palermo  
Italy  
90129  
00393334231812  
matt.rossi17@virgilio.it

## Additional identifiers

**Protocol serial number**  
1/2015

## Study information

**Scientific Title**  
Evaluation of the upper limb lymphatic system: a prospective lymphoscintigraphic study in melanoma patients and healthy controls

**Study objectives**  
Current research on the upper limb lymphatic system mainly focuses on breast cancer patients with unilateral lymphedema. In the absence of a preoperative lymphoscintigraphy, the contralateral limb is used as a control, assuming that it is functionally intact. Criteria for lymphatic dysfunction include asymmetric and delayed (>10-30 minutes) transportation time of the radiopharmaceutical. Few lymphoscintigraphic studies have been conducted on patients

before any axillary surgical treatment. The aim of this study is to evaluate, through lymphoscintigraphy, the function of lymphatics in individuals with an intact lymphatic system in order to answer the following questions:

1. Is the contralateral "healthy" arm of patients with BCRL be a reliable model to investigate the physiologic lymphatic function?
2. Is there any lymphoscintigraphic pattern that we can consider physiologic or pathologic and predisposing to lymphedema?
3. Is lymphoscintigraphy a reliable test to evaluate the susceptibility to lymphedema?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

University Hospital of Palermo Ethics Committee, 19/01/2016, ref: 1/2015

### **Study design**

Prospective interventional study

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Melanoma

### **Interventions**

All subjects from the two groups will undergo lymphoscintigraphy according to the protocol described below:

1. 1 mCi (37 MBq) of <sup>99m</sup>Tc-labeled nanocolloidal albumin (Nanocoll) in a volume of 0.2 ml simultaneously injected intradermally in the second web space of both hands by two experienced nuclear radiologists
2. With the participant lying supine, gamma camera images of the upper limbs are obtained at 20, 60, and 120 minutes after injection.

In relation to the Time of Appearance of the Tracer (TAT), the lymphatic function of each upper limb are classified into three lymphoscintigraphic patterns: Type I= TAT: 20 minutes; Type II= TAT: 60 minutes; type III= TAT: 120 minutes.

### **Intervention Type**

Other

### **Primary outcome(s)**

Upper limb lymphatic function measured through lymphoscintigraphy and using the Time of Appearance of the Tracer (TAT) to the axillary nodes at 20, 60 and 120 minutes

### **Key secondary outcome(s))**

N/A

### **Completion date**

29/02/2016

## Eligibility

### Key inclusion criteria

Study group: melanoma patients:

Inclusion criteria:

1. Recent histological diagnosis of trunk or upper limbs melanoma;
2. No history or clinical findings of lymphedema, venous incompetence or trauma on the upper limbs;
3. Candidates for sentinel lymph node biopsy (SLNB);
4. Age between 18 and 75 y.o.
5. BMI between 20 and 35 kg/m<sup>2</sup>

Control group: healthy volunteers:

1. Age between 18 and 75 years
2. BMI between 20 and 35 Kg/m<sup>2</sup>
3. Males and females

### Participant type(s)

Mixed

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Key exclusion criteria

Study group: melanoma patients:

1. Lung, brain, bones metastasis
2. History or clinical findings of lymphedema, venous incompetence or trauma on the upper limbs.
3. Previous surgery on the upper limbs
4. Allergy to the radiotracer

Control group: healthy volunteers:

1. Pregnancy
2. Allergy to the radiotracer

### Date of first enrolment

01/05/2013

### Date of final enrolment

01/06/2015

## Locations

### Countries of recruitment

Italy

### Study participating centre

#### University of Palermo

Department of Surgical, Oncological and Oral Sciences

Plastic and Reconstructive Surgery

Via del Vespro, 129

Palermo

Italy

90129

## Sponsor information

### Organisation

University of Palermo

### ROR

<https://ror.org/044k9ta02>

## Funder(s)

### Funder type

University/education

### Funder Name

Università degli Studi di Palermo

### Alternative Name(s)

Palermo University, University of Palermo

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

Italy

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not expected to be made available