ISRCTN12987051 https://doi.org/10.1186/ISRCTN12987051

Evaluation of the upper limb lymphatic system

Submission date
01/03/2016

Recruitment status
No longer recruiting

Registration date
11/03/2016

Overall study status
Completed

Last Edited
11/03/2016

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 though 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
http://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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 99mTc-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 measure
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

Secondary outcome measures
N/A

Overall study start date
01/04/2013

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/m2

Control group: healthy volunteers:
1. Age between 18 and 75 years
2. BMI between 20 and 35 Kg/m2
3. Males and females

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Study group: 20 patients (40 upper limbs); Control Group: 10 healthy volunteers (20 upper limbs)

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

Sponsor details
Department of Surgical, Oncological and Oral Sciences
via del vespro, 129

Palermo
Italy
90129

Sponsor type
University/education

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

Publication and dissemination plan
Planned publication of a study protocol and results paper in an international peer-reviewed scientific journal

Intention to publish date
30/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available