# Pilot study on robot-assisted microsurgical lymphatico-venular anastomosis

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This pilot study assesses the performance of a robot-assisted microsurgery. Lympho-venular anastomosis(LVA) is the most difficult procedure in microsurgery at this moment. This LVA technique is applied to treat for example breast cancer related...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

## Summary

### ID

NL-OMON55850

**Source** ToetsingOnline

Brief title Robotic LVA study

### Condition

• Skin and subcutaneous tissue therapeutic procedures

Synonym lymphedema

**Research involving** Human

### **Sponsors and support**

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W

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### Intervention

Keyword: anastomosis, lymphatico-venular, microsurgery, robotic

### **Outcome measures**

#### **Primary outcome**

Primary outcome parameter is LVA anastomosis technique and the quality of the anastomosis.

#### Secondary outcome

Secondary outcome measures include duration of surgery, technical errors during

surgery & complications peri-operatively, surgeon\*s satisfaction with the LVA

procedure, surgeon\*s learning curve with the procedure in practise, the

patients\* convenience during surgery, arm volume over time and patient\*s

symptom development over time.

## **Study description**

#### **Background summary**

Microsurgery facilitates procedures such as transplantation of tissue as well as lymph oedema treatment. Currently the surgeon\*s hands are the limiting factor in microsurgical performance. Robot-assistance increases the movement precision and might therefore be of great importance for the advancement of microsurgery in the world.

#### **Study objective**

This pilot study assesses the performance of a robot-assisted microsurgery. Lympho-venular anastomosis(LVA) is the most difficult procedure in microsurgery at this moment. This LVA technique is applied to treat for example breast cancer related lymph oedema. Therefore, this LVA procedure is compared using a manual expert and the same expert applying robot assisted LVA.

#### Study design

A prospective pilot study in Maastircht University Medical Center assesses twenty patients to undergo either robot assisted (n=30) or manual LVA (n=30) to treat the BRCLA. Primary outcome parameter is LVA anastomosis technique. Secondary outcome measures include duration of surgery, technical errors during surgery & complications peri-operatively, surgeon\*s satisfaction with the LVA procedure, the patients\* convenience during surgery, arm volume over time and patient\*s symptom development over time.

#### Intervention

LVA is a minimally invasive procedure, which can be performed under local anaesthesia. The indocyanine green (ICG) is injected into the second and fourth finger webspace of the lymphedematous limb. Next, ICG lymphangiography is performed. Using the photographs as a guide and the ICG angiography, the injection sites fluorescent stains are identified. The patient\*s limb is then prepared for surgery.

Before making the incision, a mix of lidocaine and epinephrine is injected at the site of incision to achieve local anaesthesia and optimal haemostasis.

Based on the ICG lymphangiography mapping incisions of 1.5 to 2 cm are made at the predetermined sites. Lymphatic vessels are identified. When a viable lymphatic vessel is identified it is end-toend anastomosed to a similarly sized adjacent recipient venule in the subdermal plane.

Generally 1 to 3 anastomoses are made in a lymphedematous arm. The surgery takes approximately two hours.

The robot assists the surgery implying that the movements of the surgeon are delayed. The same instruments are used and surgery steps are identical to the manual technique.

### Study burden and risks

The robot holds the microsurgical instruments and is extensively tested in the laboratory and on animals. It has not shown any negative side effect compared to the experienced manual LVA techniques.

## Contacts

#### Public

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## **Trial sites**

## **Listed location countries**

Netherlands

## **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

## **Inclusion criteria**

- Female gender
- Age 18 years or older
- Treated for primary early stage breast cancer
- Early stage lymphedema of the arm (stage 1 or 2 on ISL classification)
- ELV >=10%
- Suffering unilateral disease and treatment

## **Exclusion criteria**

- Male gender
- Stage 3 lymphedema of the arm
- Recurrent breast cancer
- Distant breast cancer metastases
- Current substance abuse
- History of marcaine or indocyanine green allergy
- Non-viable lymphatic system as determined by near infrared imaging
- Previous LVA in the arm with lymphedema (<10 years)

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	17-08-2017
Enrollment:	60
Туре:	Actual

## Medical products/devices used

Generic name:	robot to assist microsurgery
Registration:	Yes - CE intended use

## **Ethics review**

Approved WMO Date:	31-05-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	18-01-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

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Date:	26-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	02-07-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 26829 Source: Nationaal Trial Register Title:

### In other registers

**Register** CCMO Other ID NL60199.068.16 NL6291