Robot geassisteerde LVA: een pilot studie naar robot-geassisteerde microchirurgische lymfatico-veneuze anastomoses

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26829

Source
NTR

Brief title
Robotic LVA study

Health condition

lymphedema
robotic (super)microsurgery
lymphatico-venular anastomosis (LVA)

lymfoedeem
robot-geassisteerde (super)microchirurgie
lymphatico-veneuze anastomose (LVA)

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Microsure

Intervention

Outcome measures

Primary outcome

Quality of the anastomosis

Secondary outcome

Duration of the surgery
Errors during surgery & peri-operative complications
Surgeons' satisfaction with the procedure
Patients' convenience during the surgery
Arm volume over time
Patients' symptoms over time

Study description

Background summary

Microsurgery facilitates procedures such as transplantation of tissue as well as lymphedema 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.
This pilot study assesses the performance of robot-assisted microsurgery. Lymphatico-venular anastomosis is the most difficult procedure in microsurgery at this moment (i.e. supermicrosurgery). This LVA technique is applied to treat for example breast cancer related lymphedema (BCRL). Therefore, this LVA procedure is compared using a manual expert and the same expert applying robot assisted LVA.

Study objective

A newly, dedicated robotic system for (super)microsurgery can increase efficiency and precison of microsurgical skills.

Study design

Primary and secondary outcomes will be assessed during (and after) surgery.

Intervention

Robot-assisted LVA versus Conventional LVA

Contacts

Public
P. Debyelaan 25
R.M. Schols
Maastricht 6229 HX
The Netherlands
+31 (0)43 3881575
Scientific
P. Debyelaan 25
R.M. Schols
Maastricht 6229 HX
The Netherlands
+31 (0)43 3881575

Eligibility criteria

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 ¡Ý10%

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55850
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6291
NTR-old	NTR6465
CCMO	NL60199.068.16
OMON	NL-OMON55850

Study results

Summary results
https://www.ncbi.nlm.nih.gov/pubmed/28265793