Robot geassisteerde microchirurgische vrije lap reconstructie van de onderste extremiteit: een haalbaarheidsstudie

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22584

Source
NTR

Brief title
Robotic Free Flap

Health condition

Free flap, reconstruction, lower extremity, microsurgery

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Robot is provided/created by MicroSure

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to demonstrate the clinically applicable use of robot-assistance in lower extremity free-flap reconstruction. The primary outcome is the quality of the anastomosis using Structured Assessment of Microsurgery Skills (SAMS).

Secondary outcome

To provide important surgical and technical information, and to collect patient and surgeon satisfaction, the following secondary outcome measures are gathered:

• Duration of surgery (duration of the anastomosis and total surgery duration)

• Intra-operative and post-operative complications

• Surgical errors during the operation

• Surgeon’s satisfaction with the applied technique (VAS score)

• Flap success rate, reoperations, complications

• Patients’ satisfaction with the procedure (VAS score)

• Patient’s functional ability

Study description

Background summary

Lower extremity reconstruction is a field of plastic surgery that aims to restoring/maintaining limb function as well as ensuring optimal cosmetic outcomes. Recent advances in plastic surgical technique as well as the introduction of microvascular free tissue transfer has revolutionized this field, allowing the salvage of limbs that would have otherwise been amputated. Free tissue transfer is often needed when there is significant soft tissue loss with exposed bone, tendon, and blood vessels. Currently this operation is done by hand, were the hand is the limiting factor performing this technique. In cooperation with the Technical University in Eindhoven, and Maastricht University Medical Center, a new robotic platform has been developed. The primary objective of this study is to demonstrate the clinically applicable use of robotic-assistance in lower extremity free-flap reconstruction.

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

Robotic-assisted anastomose of the artery/veins/nerves of the free flap to reconstruction site

Contacts

Public
MUMC
A. Scharmga
Maastricht 6202 AZ
The Netherlands
0031433875496
Scientific
MUMC
A. Scharmga
Maastricht 6202 AZ
The Netherlands
0031433875496

Eligibility criteria

Inclusion criteria

- Any patient (>18 years or older) with an indication of lower extremity free-flap reconstruction.

Exclusion criteria

- Unable to provide informed consent (i.e. mentally unwell)

- Individual may not complete follow up for any reason.

- Patients younger than 18 years of age

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54625
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6872
NTR-old	NTR7050
CCMO	NL64506.068.17
OMON	NL-OMON54625

Study results