Robotic-assisted microsurgical free flap reconstruction of the lower extremity; a feasibility study

Published: 17-05-2018
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The primary objective of this study is to demonstrate the clinically applicable use of robotic-assistance in lower extremity free-flap reconstruction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54625

Source
ToetsingOnline

Brief title
Robotic-assisted microsurgical free flap reconstruction

Condition

- Vascular therapeutic procedures

Synonym
free flap reconstruction of the lower extremity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: free flap, microsurgery, robotic

Outcome measures

Primary outcome

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 in performing this technique. In

cooperation with the Technical University in Eindhoven (TuE) and Maastricht University Medical Center (MUMC+), a new robotic-platform has been developed.

Study objective

The primary objective of this study is to demonstrate the clinically applicable use of robotic-assistance in lower extremity free-flap reconstruction.

Study design

A prospective study assesses ten patients who will undergo robotic-assisted microsurgical free flap reconstruction of the lower extremity.

Intervention

A large part of the operation follows the normal procedure. During suturing of the bloodvessels/nerves (anastomoses) robotic-assistance will be used.

Study burden and risks

A similar study has not yet been performed. However, the robot has been extensively tested in the laboratory and on animals, and currently a pilot study has started for lymphatico-venular anastomosis. Participating surgeons will be sufficiently trained using the robot.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

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

Exclusion criteria

- Indication of more than one free flap
- 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	02-07-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	17-05-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-08-2024
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: 22584
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL64506.068.17
OMON	NL-OMON22584