Robotic-assisted microsurgery in digital replantation in patients with traumatic digital amputation; a feasibility study

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To assess the applicability of robotic-assisted microsurgery in replantation of amputated digits due to trauma.

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

Summary

ID

NL-OMON56234

Source
ToetsingOnline

Brief title
Robotic-assisted microsurgery in digital replantation

Condition

- Vascular therapeutic procedures

Synonym
amputated finger

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: digit, microsurgery, replantation, robotic

Outcome measures

Primary outcome

The primary objective is to study the applicability of robotic-assisted microsurgery in replantation of amputated digits due to trauma. The primary outcome will be the quality of the anastomoses 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:

- Survival of the replanted digits;

- Duration of surgery;

- Adverse events, complications and robotic errors peri-operatively;

- Post-operative complications and adverse events;

- Surgeon*s satisfaction with the technique applied;

- Patient*s satisfaction with the surgery procedure;

- Function of the hand over time.

Study description

Background summary

Microsurgery requires great skill and is limited by the precision and physiological tremor of the operating surgeon. Robotic-assistance could be of benefit in microsurgical procedures by increasing the precision during the operation. Currently we are performing robotic-assisted microsurgery in

lymphatico-venular anastomosis (LVA), with the next step being expanding the use of the robotic-assisted microsurgery to replantation of amputated digits. Digital replantation requires great precision as very small vessels and nerves have to be repaired.

Study objective

To assess the applicability of robotic-assisted microsurgery in replantation of amputated digits due to trauma.

Study design

A prospective feasibility study assesses 5 patients with traumatic amputation of one or more digits to undergo robot assisted repair. The primary outcome will be the quality of the anastomoses using Structured Assessment of Microsurgery Skills (SAMS). Secondary outcome measures include survival, duration of the surgery, adverse events, complications peri-operatively, the surgeon*s satisfaction and the Michigan Hand Outcomes Questionnaire (MHQ).

Intervention

Large part of the surgery follows the normal procedure. The robotic-assisted part of operation is as follows:
After preparation of the nerves, arteries and veins, the robot will be used to reconnect these structures with robotic assistance. It is up to the treating surgeon to determine the amount of arteries and veins that will be reconnected to get optimal perfusion of the replanted digit.
The operating surgeon will decide which vessels and nerves will be reconnected and how many of these repairs will be done with robotic-assistance. Patient characteristics, the quality of the traumatised tissues, ischaemia time and operating time and patient position will be important factors in this decision.

Study burden and risks

A similar study in robotic- assisted replantation of an amputated digit has not yet been performed with this first robotic platform for microsurgery. However, the robot has been extensively tested in the laboratory and on animals, and currently the robot is used for robotic-assisted LVA in a pilot study. Participating surgeons will be sufficiently trained to use 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- 18 years of age or older
- Traumatic amputation of one or more digits;
- Dutch resident (due to follow-up);
- Time from trauma to presentation is less than 6 hours;
- Amputated finger is feasible for replantation;
- Patient request replantation over *simple* wound repair with revision amputation.

Exclusion criteria

In het Engels
A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Additional significant trauma that dictates other treatment priorities
- Patient is not able to understand the study and consent for the operation

- Current substance abuse;
- Inability to replant the digit for any reason;
- Unable to finish follow-up for any reason.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2024
Enrollment:	5
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	06-10-2023
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL81387.068.22