Robot geassisteerde microchirurgie in replantatie van de vinger na trauma; een haalbaarheidsstudie

No registrations found.

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

Summary

ID

NL-OMON25093

Source Nationaal Trial Register

Brief title Robot REPLANT

Health condition

Robotic-assistance in replantation of an amputated digit after trauma

Sponsors and support

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

Intervention

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).

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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. Currently it is nearly impossible to repair veins and/or nerves in zone 1 (Tamai classification) amputations, hence there might be a place for a microsurgical robot. As it filters out the physiological tremor of the surgeon, it can be 10 times more precise than manual surgery. The purpose of this study is to investigate whether robot-assisted microsurgery is safe and if the use of the robot is beneficial.

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.

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Intervention

Robotic-assisted anastomose during replantation of amputated digit after trauma

Contacts

Public

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Eligibility criteria

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

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

Recruitment

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Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	5
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description None

Ethics review

Not applicable Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48976 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6873
NTR-old	NTR7051
ССМО	NL64164.068.17
OMON	NL-OMON48976

Study results