Robot geassisteerde microchirurgie in patiënten met zenuw schade in de vinger: een haalbaarheidsstudie

No registrations found.

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

Summary

ID

NL-OMON25767

Source
Nationaal Trial Register

Brief title
Robotic DNR study

Health condition

microsurgery, digital nerve repair

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 is to study the applicability of robotic-assisted microsurgery in DNR after trauma. The primary outcome is the quality of the anastomosis using 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;

- 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;

- Recovery of sensation in the injured nerve;

- Function of the hand over time.

Study description

Background summary

During microsurgical performances, the surgeon’s hands always have a small physiological tremor, which limits precision. Hence, to improve movement precision, robotic-assisted microsurgery might be of great importance. Currently we are performing robotic-assisted microsurgery in lymphatico-venular anastomosis, with the next step being expanding the use of the robotic-assisted microsurgery to digital nerve repairs.

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 damaged nerve

Contacts

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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 digital nerve injury to one or more fingers;

- Dutch resident (due to follow-up);

- Time from trauma to presentation at the hospital is less than 24 hours.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Amputation of an injured finger for which replantation is indicated

- Previous injury or operation of the damaged nerve, or brachial plexus damage;

- Crush injuries;

- Additional fractures at the nerve injury site;

- Current substance abuse;

- 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

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: 54692

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6871
NTR-old	NTR7049
CCMO	NL64178.068.17
OMON	NL-OMON54692

Study results