Robotic-assisted microsurgery in patients with digital nerve injuries; a feasibility study

Published: 17-05-2018
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This study will assess the applicability of robotic-assisted microsurgery in DNR after trauma.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54692

Source
ToetsingOnline

Brief title
Research protocol Robotic-assisted microsurgery in digital nerve injuries

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
digital nerve repair

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: Microsurgery, Nerve injury, Robot

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 (LVA), with the next step being expanding the use of the

robotic-assisted microsurgery to digital nerve repairs (DNR).

Study objective

This study will assess the applicability of robotic-assisted microsurgery in DNR after trauma.

Study design

In a prospective feasibility study ten patients with traumatic digital nerve injury will undergo robotic-assisted repair of the damaged nerve(s). The primary outcome is the quality of anastomoses using Structured Assessment of Microsurgery Skills (SAMS). Secondary outcome measures include long term sensibility, duration of the surgery, adverse events, complications peri-operatively, the surgeon*s satisfaction and the function of the injured hand.

Intervention

Using the Microsure robot the nerve is repaired with ethilon 9.0 or 10.0 sutures after debridement of the wound and the nerve ends.
The amount of sutures and indication for primary repair of the nerve laceration is decided by the operating microsurgeon. Additional vascular or tendon injury will be repaired in the same operation.

Study burden and risks

A similar study in robotic- assisted nerve repair has not yet been performed with this first robotic platform for microsurgery. However, the robot has been extensively tested in preclinical trials. 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 digital nerve injury (N. digitalis propria or N. digitalis communis) 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;
- Previous injury or operation in the damaged nerve, or brachial plexus damage;
- Crush injuries;
- Additional fractures at the injured site;
- Current substance abuse;
- 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):	20-04-2021
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	a robot to assist 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

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: 25767
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64178.068.17
Other	NTRnr volgt