

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

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A newly, dedicated robotic system for (super)microsurgery can increase efficiency and precision of microsurgical skills

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25093

Bron

Nationaal Trial Register

Verkorte titel

Robot REPLANT

Aandoening

Robotic-assistance in replantation of an amputated digit after trauma

Ondersteuning

Primaire sponsor: Maastricht University Medical Center

Overige ondersteuning: The robot is provided/created by MicroSure

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

A newly, dedicated robotic system for (super)microsurgery can increase efficiency and precision of microsurgical skills

Onderzoeksopzet

Primary and secondary outcomes will be assessed during (and after) surgery.

Onderzoeksproduct en/of interventie

Robotic-assisted anastomose during replantation of amputated digit after trauma

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2018
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

None

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48976

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten