Pain and patient-reported outcome associated with surgery for carpal tunnel syndrome or trigger finger under local anesthesia with and without tourniquet

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48016

Source
ToetsingOnline

Brief title
CTR or TFR with or without tourniquet

Condition

- Other condition
- Peripheral neuropathies

Synonym
1.) Carpal tunnel syndrome, median neuropathy. 2.) Stenosing tenosynovitis, trigger finger

Health condition

Carpale tunnel syndroom, tenovaginitis stenosans

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Afdeling plastische chirurgie van het JBZ

Intervention

Keyword: Carpal tunnel release, tourniquet, Trigger finger release, WALANT

Outcome measures

Primary outcome

Pain during the surgery on a 0-10 numeric rating scale

Secondary outcome

Patient-reported outcome measures:

- QuickDASH

- BCTQ

- Postoperative complications

Study description

Background summary

Elective hand surgery such as carpal tunnel release and trigger finger release can be performed in the outpatient clinic with local anesthesia and tourniquet. A tourniquet is used for controlled exsanguination of the limb during surgery to minimize blood loss and increase visibility in the surgical field. The tourniquet, however, may be uncomfortable or even painful for the patient. In *Wide-Awake, Local Anesthesia, No Tourniquet* (WALANT) surgery, adrenalin is used for local vasoconstriction (Lalonde, 2017). Within the plastic surgery department of the JBZ hospital, both WALANT and tourniquets are used during hand surgery at the discretion of the surgeon.

Study objective

The aim of this study is to compare pain or discomfort during the ingreep between WALANT and tourniquet use.
In addition, we aim to determine whether carpal tunnel release or trigger finger release using WALANT has an effect on recovery, patient-reported outcome on the short and long term, and rate of postoperative complications. The information can be used to recommend the use of WALANT during minor hand surgery in the nationwide protocol.

Study design

Randomized controlled trial

Intervention

Application of a tourniquet during regular surgery

Study burden and risks

Burden: questionnaires at 4 timepoints, max 5 minutes each time.
Risk: negligible.

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

Operative treatment for carpal tunnel syndrome or stenosing tenosynovitis

Exclusion criteria

Coagulopathy or use of vitamin K antagonist that may not be temporary withdrawn
Recurrent or persisting CTS or TVS
Axillary lymph node dissection of the affected limb

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2019
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	04-11-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL68903.028.19

Study results

Date completed:	10-08-2021
Actual enrolment:	142