EVOCU Trial: Endoscopic Versus Open CUbital tunnel release

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29442

Source
NTR

Brief title
EVOCU Trial

Health condition

Cubital Tunnel Syndrome

Sponsors and support

Primary sponsor: EPA vd Heijden Plastic Surgeon, MD, PhD, Jeroen Bosch Hospital, 's-Hertogenbosch, the Netherlands; PN Sprangers, MD, Jeroen Bosch Hospital, 's-Hertogenbosch
Source(s) of monetary or material Support: Stipendium Price Jeroen Bosch Hospital, 's-Hertogenbosch, the Netherlands

Intervention

Outcome measures

Primary outcome

To compare the change in BCTQ between open and endoscopic cubital tunnel release using the BCTQ at 3, 12 and 18 months postoperatively.

Secondary outcome

- To compare the change in PRUNE between open and endoscopic cubital tunnel release compared to the score of the BCTQ at 3, 12 and 18 months postoperatively;
- To compare the PREM between open and endoscopic cubital tunnel release 3 months postoperatively, and its association with PROM;
- To compare the post-operative recovery of sensibility between open and endoscopic cubital tunnel release at 3 and 12 months postoperatively;
- To compare the return to work/full function in days between open and endoscopic cubital tunnel release;
- To compare the complications between open and endoscopic cubital tunnel release in the 18 month follow-up period;
- To compare the scar aesthetics between open and endoscopic cubital tunnel release at 6 weeks and 12 months postoperatively;
- To compare the correlation between VAS score, Bishop score, two-point discrimination and both PROMS (BCTQ and PRUNE).

Study description

Background summary

Background
Cubital tunnel syndrome is the second most common entrapment neuropathy of the upper extremity after carpal tunnel syndrome. For surgical decompression, two methods are being used in common practice: an open or an endoscopic release. There is ongoing debate as to what constitutes the superior surgical approach. So far, only objective outcomes have been studied and these studies have not been randomised. Moreover, these objective measures might not adequately reflect the succes of the surgical procedure. This study therefore aims to determine efficacy of open and endoscopic cubital tunnel release in terms of patient reported outcome measures, patient reported experience measures and complications.

Methods
This prospective single-center open randomised trial will include 160 patients with clinically objectified cubital tunnel syndrome and will take 18 months from baseline. Patients are randomised to receive cubital tunnel release using the open or endoscopic approach. The surgeon and patients are not blinded for treatment allocation. The trial will take place at the Plastic Surgery Department of the Jeroen Bosch Hospital, the Netherlands.

Discussion
Currently, the choice for one of the methods is based on surgeon’s preferences and degree of familiarity with a particular technique, which is mostly the open technique on the assumption that this is easier, faster and cheaper. The theoretical benefits of an endoscopic release include a less invasive surgical technique, reduced nerve complications and decreased scar discomfort. PROMs and PREMs have potential to improve the quality of services and that

better health care experiences are associated with better clinical outcome in self-reported postsurgical questionnaires. Combining subjective measures with objective outcomes, efficacy, patient treatment experience and safety profile could help differentiating between open and endoscopic cubital tunnel release. This could aid clinicians in evidence based choices towards the best surgical approach in patients with cubital tunnel syndrome.

Study objective

We hypothesise that open and endoscopic cubital tunnel release have a different effectiveness in treating cubital tunnel syndrome in both primary and secondary outcomes. Since the RCTs performed were of moderate-quality and consists of a relatively low number of patients, the American Society for Surgery of the Hand (2018) states that research data on the optimal surgical treatment for cubital tunnel syndrome remains inconclusive. A more large-sample, high- quality RCT is needed to verify the outcomes.

Study design

- Before baseline - demographics, disease history, disease characteristics, physical examination, EMG
- Baseline (surgery) - PROMS (BCTQ and PRUNE), surgical characteristics
- 2 weeks - pain (VAS), complications
- 6 weeks (phone call) - pain (VAS), RTW, complications, Bishop
- 3 months - pain (VAS), RTW, complications, Bishop, PREM, two-point discrimination, PROMS (BCTQ and PRUNE)
- 12 months - pain (VAS), RTW, complications, Bishop, two-point discrimination, PROMS (BCTQ and PRUNE), POSAS
- 18 months (online) - pain (VAS), PROMS (BCTQ and PRUNE)

Intervention

Open cubital tunnel release and endoscopic cubital tunnel release.

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:
- Idiopathic ulnar nerve entrapment at elbow, objectified clinically, with an electrophysiologic confirmed (EMG) diagnosis;
- Ability to measure the outcome of the study in this patient (e.g. life expectancy > 1 year, no planned relocation);
- Ability to speak and understand Dutch;
- Informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Age under 18;
- Not able to provide informed consent;
- Previous surgical cubital tunnel release or other surgery performed in the same elbow;
- Subluxation palpable during elbow flexion pre-operatively or occurring during surgery after release for which a transposition of the ulnar nerve is needed.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	10-06-2021
Enrollment:	160
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50856
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9556
CCMO	NL75666.028.20
OMON	NL-OMON50856

Study results