EVOCU Trial: Endoscopic Versus Open CUbital tunnel release

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29442

Bron
NTR

Verkorte titel
EVOCU Trial

Aandoening

Cubital Tunnel Syndrome

Ondersteuning

Primaire sponsor: EPA vd Heijden Plastic Surgeon, MD, PhD, Jeroen Bosch Hospital, 's-Hertogenbosch, the Netherlands; PN Sprangers, MD, Jeroen Bosch Hospital, 's-Hertogenbosch
Overige ondersteuning: Stipendium Price Jeroen Bosch Hospital, 's-Hertogenbosch, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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)

Onderzoeksproduct en/of interventie

Open cubital tunnel release and endoscopic cubital tunnel release.

Contactpersonen

Publiek

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Wetenschappelijk

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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:

- 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.

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:
- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-06-2021
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50856
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten