Endoscopic versus Open Cubital Tunnel Release: An Open Randomized Clinical Trial

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To make an evidence-based recommendation on which method has the best efficacy (PROM), patient treatment experience (PREM) and safety profile (complications).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON50856

Source
ToetsingOnline

Brief title
EVOCU Trial: Endoscopic Versus Open CUbital tunnel release

Condition

- Peripheral neuropathies
- Nervous system, skull and spine therapeutic procedures

Synonym
compression of the nerve at the elbow, Cubital Tunnel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Plastische Chirurgie
Source(s) of monetary or material Support: Afdeling Plastische Chirurgie in het Jeroen Bosch Ziekenhuis voor administratieve kosten en de Stipendum Beurs (15000) van het Jeroen

Bosch Ziekenhuis voor personeelskosten voor een arts-onderzoeker.

Intervention

Keyword: Cubital tunnel release, Cubital tunnel syndrome, Nerve decompression, Ulnar nerve

Outcome measures

Primary outcome

The difference in change (Δ, preoperatively and postoperatively) in BCTQ score

between both treatment groups at 3, 12 and 18 months follow-up.

Secondary outcome

- The difference in change (Δ, preoperatively and postoperatively) in PRUNE

score between both treatment groups at 3, 12 and 18 months follow-up;

- The difference in PREM between both treatment groups at 3 months follow-up

and its correlation with the change (Δ, preoperatively and postoperatively) in

PROM;

- The difference in post-operative recovery of sensibility between both

treatment groups at 3 and 12 months follow-up;

- The difference in return to work/full activity in days between both treatment

groups;

- The difference in amount of complications between both treatment groups

during the follow-up period of 18 months;

- The difference in scar aesthetics between both treatment groups at 6 weeks

and 12 months follow-up;

- The difference in correlation between VAS score, Bishop score,

two-point discrimination and both PROMS (BCTQ and PRUNE).

Study description

Background summary

Cubital tunnel syndrome is the second most common entrapment neuropathy of the upper extremity after carpal tunnel syndrome. The complaints can consist of pain, tingling and reduced or no feeling in the ring finger and little finger, loss of strength, reduced fine motor skills and contractures of the hand. If conservative treatment fails to improve symptoms, surgery is indicated.
Surgical cubital tunnel decompression is performed 7500 per year in the Netherlands. For surgical decompression, two methods are being used in common practice: an open release or an endoscopic release. The endoscopic approach was introduced in the early 1990s because it is less invasive; meaning a smaller skin incision and less soft tissue damage. Potential benefits include faster recovery and less risk of damage of the ulnar nerve and its side branches due to better vision during surgery. Another possible benefit is a better treatment experience by the patients, partly because of image reproduction of the operation.
There is ongoing debate as to what constitutes the superior surgical approach. Currently, the choice for one of the methods is based on surgeon*s preference based on the surgeon*s degree of familiarity and confidence with a particular technique which is mostly the open technique on the assumption that this is easier, faster and cheaper.
Few meta-analyses are performed in which the two surgical techniques are compared. These analyses are based on low- to moderate-quality retrospective observational studies and only three prospective studies. All three prospective studies found no differences between the endoscopic and open technique considering clinical results and patient satisfaction. However, these findings should be interpreted with caution as only two studies are randomized. Also, the follow-up period differed and the number of included patients is relatively small and the authors concluded that larger randomized controlled trials (RCTs) are needed to confirm their results.
So far, only outcome measures such as symptom reduction, pain and patient satisfaction have been used and no validated patient reported outcome and experience measures (PROMs / PREMs), despite the fact that the value of these outcome measures in improving quality of care has already been proven. These outcomes are particularly important since objective measures might not adequately reflect success of a surgical procedure. Modern medicine is shifting towards feedback of patients and having a better understanding of patients* experience. Therefore, including these measurements in trials is an important addition to the current literature.
The American Society for Surgery of the Hand (2018) states that research data on the optimal surgical treatment for cubital tunnel syndrome remains inconclusive. In addition, the Dutch guideline is based on the limited scientific literature of low quality. Therefore, we want to perform a

high-quality RCT with sufficient power to compare the clinical effect (PROMs) and treatment experience (PREM) of the open and endoscopic decompression.

Study objective

To make an evidence-based recommendation on which method has the best efficacy (PROM), patient treatment experience (PREM) and safety profile (complications).

Study design

This is an open randomized controlled trial. The follow-up will be 18 months from baseline. All eligible patients will be asked to participate in this study and will receive additional information. If informed consent is obtained, patients are randomized to receive cubital tunnel release using the (1) open or (2) endoscopic approach. The surgeon and patients are not blinded for treatment allocation.

Intervention

An open or endoscopic cubital tunnel release. Both the open and endoscopic cubital tunnel release are common clinical practice in patients having cubital tunnel syndrome. In the Jeroen Bosch Ziekenhuis, both types of surgery are performed on a regular basis.

Study burden and risks

There is no other difference in benefit nor risk for the individual patient compared to the treatment of cubital tunnel syndrome in common practice since both treatment arms are currently standard practice. Published data will be fully anonymised.

After this study, we hope to conclude which type of surgery is most effective in the treatment of cubital tunnel syndrome. A long-term benefit will therefore be enhancement of the quality of care and cost-effective for patient and community. However, this is no direct benefit for the participant itself.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion 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

- 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:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2022
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	24-03-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-01-2024
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

ID: 29442
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75666.028.20
OMON	NL-OMON29442