Immobilisation and scar tissue repair after open carpal tunnel release

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To determine wether the results of CTR are influenced by postoperative immobilisation of the wrist during nights. Secondly we want to determine wether scar tissue forming is influenced by the technique used to close the wound. (simple vs Donati...

Ethical review	Approved WMO
Status	Pending
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32750

Source
ToetsingOnline

Brief title
CTR

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
Compression of the median nerve. Nerve-entrapment at the wrist.

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: eigen onderzoeksfonds

Intervention

Keyword: Carpal Tunnel Release (CTR), Carpal Tunnel Syndrome (CTS), Immobilisation, Scar tissue repair

Outcome measures

Primary outcome

1) Function (DASH: Disabilities of Arm Shoulder and Hand). 2) Satisfaction

(VAS-scale). 3) Pain (VAS-scale). 4) Sensibility (2-points discrimination).

Secondary outcome

None

Study description

Background summary

Carpal Tunnel Syndrome (CTS) is the most frequent diagnosed perifer mononeuropathia. When conservative treatment failes to relief the patients complaints the retinaculum flexorum is surgically released, the so called Carpla Tunnel Relase (CTR). Overall, the outcome of this procedure are very good in general. Only little research has been performed toward the treatment after CTR. Also postoperative scar tissue frequently forms a difficult problem, while complaint of CTS can return. We think that this latter problem can be solved by a different stitching technique.

Study objective

To determine wether the results of CTR are influenced by postoperative immobilisation of the wrist during nights. Secondly we want to determine wether scar tissue forming is influenced by the technique used to close the wound. (simple vs Donati stitches)

Study design

Following earlier studies a number of 50 patients will get a postoperative treatment of four weeks of immobilisation at night. The control group will also exist of a total of 50 patients, which will get the regular treatment; no immobilistion postoperative
In another 50 patients the wound will be suitered using the Donati stitches. To

compare wether there is a difference in scar tissue forming these will be compaired with 50 patients who get the regular single stitches.

Intervention

CTR

Peroperative: Single vs Donati stitches

Postoperative: Immobilisation vs no immobilisation

Study burden and risks

Same as regular CTR

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

CTS proven by physical examination and EMG

Exclusion criteria

-DM
-hypothereoidea
-wristtrauma/wristoperation
-pregnancy
-obesity

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:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	22-07-2010
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL29488.091.09