Correlation of joint stiffness and stiffness of the skin and the prevelation of carpal tunnel syndrome (CTS).

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To clarify the aetiology of CTS and prognostic factors for the development of CTS.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34953

Source
ToetsingOnline

Brief title
Stiffness in relation to carpal tunnel syndrome

Condition

- Tendon, ligament and cartilage disorders
- Peripheral neuropathies

Synonym
compression syndrome median nerve, CTS

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Carpal tunnel syndrome, Joints, Skin, Stiffness

Outcome measures

Primary outcome

Joint stiffness, skin stiffness

Secondary outcome

Physical activities, body water.

Study description

Background summary

The exact aetiology of CTS remains yet unknown. A rise in carpal tunnel pressure is well documented, but why this phenomenon occurs is yet unknown in most patients. There is an absolute or relative narrowing of the carpal tunnel, which results in a compression of the median nerve.

A relation between connective tissue composition and joint stiffness is proven. Possibly this relationship extends to a relation between connective tissue composition, joint stiffness and the prevalence of CTS. We postulate, that a stiffer flexor retinaculum (roof of carpal tunnel) will be less compliant. As a consequence of this stiffer retinaculum the pressure in the carpal tunnel will rise more quickly in stiff patients resulting in CTS-complaints.

In answering this question we will measure the stiffness of the skin and joints in patients with and compare these results with patients without CTS.

Study objective

To clarify the aetiology of CTS and prognostic factors for the development of CTS.

Study design

Four groups;
a CTS-patient group and
three control groups (tendovaginitis stenosans (TVS), M Dupuytren and traumas to the hand)

are being compared, with regard to:

1. joint stiffness,
2. skin stiffness,
3. physical activities, measured by a standardised questionnaire,
4. body water, measured by multi frequency bio-impedance measurement

Intervention

The CTS group; a normal carpal tunnel release will be performed, with an additional biopsy of the flexor retinaculum. A biopsy of excess skin is taken as well.

The patients with TVS receive regular care by the section of the pulley. A biopsy is taken from excess skin.

In patients with M. Dupuytren a regular fasciotomy will be performed and a biopsy of the skin is taken.

Patients with a trauma to the hand wil receive normal care. A biopsy of the skin is taken

Study burden and risks

CTS group, regular out-patient clinic visit on account of CTS complaints. One-off extra visit, taking 20-30 minutes in which a stiffness measurement is done, a questionnaire is taken and a body water measurement is done. The next visit the carpal tunnel release is performed as described above (interventions).

The control groups (TVS, M. Dupuytren and trauma's to the hand) will have there regular out-patient clinic visits. One extra visit, of approximately 20-30 minutes in which a stiffness measurement is done, a questionnaire is taken and a body water measurement is done. Next visit contains the operation. In the group of patients with a trauma to the hand these additional test will be performed after the treatment.

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

Clinical CTS supported by positive EMG and a positive Boston Questionnaire

Exclusion criteria

hypo/hyperthyroidea, diabetes, rheumatoid arthritis, pregnancy, body mass index (BMI)>30, anatomical deviations in hand or wrist, muscle/skeleton affections.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	21-06-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT01081860
CCMO	NL30011.100.10