Correlation of collagen compostion of the connective tissues and the prevalation of carpal tunnel syndrome (CTS).

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To clearify the etiology of CTS and prognostic factors for the development of CTS.

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON29850

Source
ToetsingOnline

Brief title
Collagen composition in relation to the 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: St. Antonius Ziekenhuis
Source(s) of monetary or material Support: TNO-PG te Leiden

Intervention

Keyword: Carpal Tunnel Syndrome, Collagen, Connective tissue compostion, Joint Stiffness

Outcome measures

Primary outcome

Stiffness, contective tissue composition, CTS

Secondary outcome

Fysical activities, body water.

Study description

Background summary

The exact etiology of CTS remains yet unknown. A rise in carpal tunnel pressure is well documented, but why this phenomenon happens is unknown in most patients.
Pathofysiological spoken there is an absolute or relative narrowing of the carpal tunnel and as a result of this a compression of the median nerve.
We postulate, that a stiffer flexor retinaculum (roof of carpal tunnel) will be less compliant and as a consequence the pressure in the carpal tunnel will rise more quickly in stiff patients resulting in CTS-complaints.
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 prevelance of CTS.

Study objective

To clearify the etiology of CTS and prognostic factors for the development of CTS.

Study design

Two groups, a CTS-patient group and a control group, are being compared, with regard to 1. Stiffness, which will be measured by a standardised method with a goniometre. 2. Fysical activities, measured by a standardised questionairre. 3. Body water, measured by multifrequency bio-impedance measurement. 4. Connective tissue composition, analysis of a skin biopsy.

Intervention

CTS group, excision facial neavus, plus carpal tunnel release with a biopsy of the flexor retinaculum.

Control group, excision facial naevus.

Study burden and risks

CTS group, regular out-patient clinic visit on account of CTS complaints. One-off extra visit, taking 20-30 minuts in which a stiffness measurement is done, a questionairre is taken and a body water measurement is done. Next visit contains the operation in which a facial naevus will be excised and a carpal tunnel release is being performed.

Control group, regular out-patient clinic visit on account of facial naevus. One-off extra visit, taking 20-30 minuts in which a stiffness measurement is done, a questionairre is taken a body water measurement is done and an EMG-investigation is done. Next visit contains the operation in which a facial naevus will be excised.

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

Group 1. Clinical CTS supported by positive EMG and a positive Boston Questionnaire, plus a benign naevus in the face.
Group 2. Healthy female persons, benign naevi in the face plus absence of CTS determined by EMG.

Exclusion criteria

Group 1. Malign tumors in the face, hypo/hyperthyroidea, diabetes, reumatoid arthritis, pregnancy, body mass index (BMI)>30, anantomical deviations in hand or wrist, muscle/skeleton affections.
Group 2. Malign tumors in the face, hypo/hyperthyroidea, diabetes, reumatoid arthritis, pregnancy, body mass index (BMI)>30, anantomical deviations in hand or wrist, muscle/skeleton affections.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	20

Type:	Anticipated

Ethics review

Approved WMO Date:	14-12-2006
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
CCMO	NL11545.100.06