Unraveling the genetic causes of carpal tunnel syndrome

Published: 10-11-2016
Last updated: 16-04-2024

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON43331

Source
ToetsingOnline

Brief title
Genetic research of CTS

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
Carpal tunnel syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Antwerpen, België
Source(s) of monetary or material Support: Europees project (SYBIL)

Intervention

Keyword: Carpal tunnel syndrome, Genetic research

Outcome measures

Primary outcome

Mutation spectrum of patients suffering from CTS

Secondary outcome

Not applicable

Study description

Background summary

Carpal tunnel syndrome (CTS) is the most common form of peripheral entrapment neuropathy with a high socio-economic impact on both patient and society. Although CTS occurs in ~4% of the population, its pathogenesis remains largely unclear. In the majority of patients no specific cause or underlying condition can be found. This idiopathic form of CTS is often clustered within families and has a heritability of 0.46, indicating that genetic factors must play a role in the pathogenesis of this disorder. The aim of our study is to further elucidate the role of genetic factors in the pathogenesis of CTS. These new insights may enhance early diagnosis and provide new therapeutic measures for CTS.

Study objective

The aim of our study is to further elucidate the role of genetic factors in the pathogenesis of CTS by genetic and functional research.

-Objective 1: Unravel the mutational spectrum of genes in patients with idiopathic CTS
-Objective 2: Evaluation of pathways of interest in carpal tunnel syndrome
-Objective 3: Study of the role of genes of interest in the pathogenesis of bone abnormalities

Study design

Blood samples will be collected from individuals with CTS for genetic research purposes. During carpal tunnel release surgery, tissue samples (skin,

subsynovial connective tissue, tranversal carpal ligament) will be collected for funtional validation of interesting genetic variants.

Study burden and risks

Burden:

- 1x informed consent
- 1x questionnaire
- 1x blood sample
- 1 x biopsy of the skin, subsynovial connective tissue, transversal carpal ligament (during carpal tunnel release, no extra incision needed)
- 1x photocopy of both hands

Risks

Giving a blood sample can be unpleasant since a needle needs to be inserted in the skin. Formation of a bruise can occur.
Since the transversal carpal ligament will be split during carpal tunnel release, no risks are involved in collecting small tissue biopsies.
Participation in the study can cause concerns about the heritability of CTS in the family. When the patient has concerns, the principal investigator can be contacted. If wanted, the investigator can contact the genetic councelor who will answer the patients questions to one's best ability. A photocopy of the hands will not have any health effects.

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

- carpal tunnel syndrome
- age: 18+

Exclusion criteria

Diabetes mellitus
• Amyloïdosis
• Hyperthyroidism
• Rheumatoid arthritis
• Acromegaly
• Lysosomal storage disease
• Obesitas
• Trauma
• Tumor at the level of the wrist
• Injections at the level of the wrist
• Pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO Date:	10-11-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	31-07-2017
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL57485.075.16