Complex Regional Pain syndrome: a (focal) small fibre neuropathy possibly related to mutations in voltage-gated sodium channels

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Peripheral neuropathies
Study type	Observational invasive

Summary

ID

NL-OMON37879

Source
ToetsingOnline

Brief title
CRPS SFN

Condition

- Peripheral neuropathies

Synonym
painful neuropathy, Peripheral neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Complex Regional Pain syndrome, - Nav1.7, - Small Fibre Neuropathy, - voltage-gated sodium channels

Outcome measures

Primary outcome

The presence of mutations in the SCN9A gene.

Secondary outcome

- The presence of mutations in SCN10A and SCN11A genes.

- Genotype to phenotypical findings (at the impairment level like pain and

fatigue severity, autonomic deficits, fatigue, and quality of life impact) of

CRPS patients having SCN9A mutations versus those who remain with an unknown

aetiology.

Study description

Background summary

Complex regional pain syndrome (CRPS) is a taxonomy describing a disease that may start spontaneously or may develop after a traumatic or iatrogenic injury. Recent studies have suggested CRPS symptoms to be related to small fibre neuropathy (SFN). The pathophysiology of CRPS remains unsolved despite these clinical observations that are being backed up by confirmatory pathological findings of SFN. CRPS shows an overlap with the SFN and erythermalgia phenotype. In both inherited erythermalgia and SFN, mutations in voltage-gated sodium channel Nav1.7 have been found. These channels are perhaps potential targets for future treatment of chronic pain.

Study objective

To determine, in patients registered at our hospital having CRPS (types I) at the leg, the percentage of patients having clinical features compatible with SFN and compared to the unaffected leg (in unilateral cases) to determine

possible focal or generalized involvement. In patients with clinical features of SFN, we will be determining the percentage of these patients having a mutation in SCN9A, encoding for Nav1.7.

Study design

All patients known at the neurological and anaesthesiological outpatient clinic of the MUMC with a diagnosis of CRPS type I fulfilling the international diagnostic criteria will be asked to participate in this study.

Study burden and risks

Patients will complete several questionnaires (estimated time 30 minutes)(addendum), and will undergo QST and skinbiopsy. QST is a noninvasive, painless test of temperature sensation. Durations of QST is 30 minutes. Skin biopsy for determination of IENF density is a minimal invasive procedure. Estimated time ~10 minutes. There is a very small risk of getting an infection. Some people get a scar at the site of the biopsy (often less than 3mm, conform the size of the punch biopsy). NCS is part of care as usual for patients with polyneuropathy.

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

Inclusion criteria
- diagnosis CRPS1 according to IASP criteria
- age > 18 years
- at least 2 or more symptoms compatible with SFN
- normal findings at neurological and EMG examination, besides changes compatible with SFN involvement.

Exclusion criteria

- Exclusion criteria:
- symptoms and signs of large fibre involvement at neurological examination
- current or previous neurologic abnormalities unrelated to reflex sympathetic dystrophy
- presence of Raynaud*s disease
- another condition affecting the function of the disease or contra-lateral extremity
- abnormal EMG findings
- diagnosis CRPSII

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:	50

Type:	Anticipated

Ethics review

Approved WMO Date:	13-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL38219.068.11