Development of Complex Regional Pain Syndrome (CRPS) Severity Score As A Clinical Tool To Monitor Disease Progression

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The primary aim of the proposed multi-site study is to determine if the CRPS Severity Score can be used as a clinical bedside tool to monitor CRPS change in symptoms over time, specifically progression or regression. Various interventions will occur…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON35516

Source
ToetsingOnline

Brief title
Development of a CRPS) Severity Score

Condition

- Peripheral neuropathies

Synonym
Dystrophy, Reflex Sympathetic Dystrophy, RSD

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: Complex Regional Pain Syndrome, CRPS, severity score

Outcome measures

Primary outcome

The CRPS severity score is the primary study variable. The objective is to

evaluate the test-retest reliablity and the responsiveness of this score.

Secondary outcome

Correlation of the change in the CRPS severity score with those of the changes

in other instruments, such as pain intensity, other pain measures and the

SF-36.

Study description

Background summary

The current proposal involves an international multi-center study that aims to develop a Complex Regional Pain Syndrome (CRPS) Severity Score as a clinical tool to monitor disease progression. The department of neurology of the LUMC is one of the 14 participants in this study. The recent pilot paper of our group suggests the need for a CRPS severity score (CSS) to compliment the dichotomous diagnosis. This should be designed to be simple and practical for any practitioner in any setting with minimal and readily available equipment and common *bedside technique*. The design we propose for empirical testing is pragmatic in that it uses the same signs and symptoms used in the diagnosis of the syndrome with a score for each item (coded 0 = absent, 1 = present) simply added to form the CSS (0-16 range). Preliminary validation techniques were used for the pilot/feasibility study which showed associations with pain intensity, emotional distress, impaired functioning, objective sensory and physical changes using the signs and symptoms CRPS database checklist and the Rand-36 Health Survey. On the basis of a post hoc analysis of the data used for developing and re-validating the diagnostic criteria, and a 10 subject prospective feasibility study, a slightly different formulation of the CSS checklist will be used for this work, based on a balanced approach: a yes/no of

2 signs and 2 symptoms in each of the 4 CRPS factors for a total score of 16 possible points (highest score = worst severity of syndrome).

Study objective

The primary aim of the proposed multi-site study is to determine if the CRPS Severity Score can be used as a clinical bedside tool to monitor CRPS change in symptoms over time, specifically progression or regression. Various interventions will occur between the two time points (separated by 3 months) to assess the sensitivity of the evolving instrument to change.

Study design

The proposed study will use elements of both a prospective correlational design and a case comparison design, and will use a coordinated multi-site data collection system.

Study burden and risks

Taking part in this study involves only negigible risks and burden mainly involves the investment of time.
There are 2 study moments of 75 minutes each for acute patients and patients whose treatment is about to change (baseline, 12 weeks) and 3 study moments of 75 minutes for patients on stable management (baseline, 2 weeks, 12 weeks).

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

Subjects who are 18 years or older, who have the cognitive abilities to understand the demands of the study, who have sufficient command of Dutch and who meet the provisional 2011 IASP CRPS Clinical Diagnostic Criteria (Revised) are included in the study. .

Exclusion criteria

Patients who do not meet the inclusion criteria, do not give informed consent and who have other conditions that may explain their signs and symptoms.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-07-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	28-11-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL37789.058.11