Validation of revised diagnostic criteria for Complex Regional Pain Syndrome.

Published: 18-03-2008
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The primary aim of the proposed multi-site study will be to determine internal and external validity of the proposed new diagnostic criteria.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Injuries by physical agents
Study type	Observational non invasive

Summary

ID

NL-OMON31995

Source
ToetsingOnline

Brief title
Validation of revised CRPS criteria.

Condition

- Injuries by physical agents
- Neurological disorders NEC

Synonym
Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van Economsche Zaken

Intervention

Keyword: Complex Regional Pain Syndrome, CRPS, diagnosis, validation.

Outcome measures

Primary outcome

Differnce in the Verschil occurence of signs and symptoms between boh patient groups.

Secondary outcome

Pain questionnaire (McGill pain questionnaire - MPQ short form), quality of life (SF-36), thermosensory assessment (TSA).

Study description

Background summary

A gold standard for the diagnosis of Complex Regional Pain Syndrome (CRPS) is not available and therefore the diagnosis is based on the presence of signs and symptoms. The criteria that are most often used worldwide are those of the International Association for the Study of Pain (IASP). The IASP criteria have been criticized for their lack of specificity, which may result in overtreatment and heterogeneous study populations. Previous work suggests that signs and symptoms of CRPS group into four relatively independent factors, only three of which are currently used in diagnosis. Revised CRPS diagnostic criteria have been proposed based on these four factors which appear to have a better balance of diagnostic sensitivity and specificity than existing criteria. The proposed adoption by the IASP of these revised diagnostic criteria necessitates their further validation. In addition, the relationship of these four diagnostic factors to hypothesized pathophysiological mechanisms in CRPS is unknown, as is their utility in predicting treatment response.
The current proposal involves an international multi-center study that aims to determine the internal and external validity of the proposed new diagnostic criteria for Complex Regional Pain Syndrome type 1 (CRPS1). The department of neurology of the LUMC is one of the ten participants in this study. The objective is to enroll 25 patients with CRPS and 25 patients with other neuropathic pain syndromes. Primary outcome measures involve the (difference in) occurrence of certain signs and symptoms. Secondary variables include pain, quality of life, and neurophysiologic parameters (detection threshold for cold

and warmth, pain thresholds for cold and warmth). Time investment for patients is approximately 2 hours. The study does not pose any risks to patients.

Study objective

The primary aim of the proposed multi-site study will be to determine internal and external validity of the proposed new diagnostic criteria.

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

In total less than 2 hours. Completing 2 questionnaires by the patient (20 minutes). Administering 3 instruments by the investigator (20 minutes). Physical examination by the asssessor (30 minutes). Neurophysiologic assessment (not painful, 20 minutes).

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

CRPS patients of 18 years and older meeting current IASP criteria.
Patients with radicular syndrome, diabethic neuropathy, postherpetic neuralgia) of 18 years and older.
No restrictions with respect to race or gender.

Exclusion criteria

With respect to both patient groups: patients with other syndromes that could account for the degree of pain and dysfunction.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL20105.058.07