

CRPS Multi site Validation Study: - Interobserver reliability using the Budapest criteria

Published: 08-12-2008

Last updated: 07-05-2024

To dermine the reliability of the newly proposed diagsotic criteria.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON31916

Source

ToetsingOnline

Brief title

CRPS Multi Site Study

Condition

- Other condition
- Neurological disorders NEC

Synonym

Complex Regional Pain syndrome, Reflex Sympathetic Dystrophy

Health condition

Chronische Pijn

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van economische zaken (BSIK)

Intervention

Keyword: Complex Regional Pain Syndrome, Diagnosis, Reliability

Outcome measures

Primary outcome

Occurrence of signs and symptoms of CRPS

Secondary outcome

Pain questionnaire (McGill pain questionnaire), quality of life, sensory assessment.

Study description

Background summary

A gold standard for the diagnosis of Complex Regional Pain Syndrome (CRPS) is lacking, and therefore the diagnosis is based on the presence of clinical signs and symptoms. The criteria that are used most often worldwide are those of the International Association for the Study of Pain (IASP), in the Netherlands the criteria by Veldman et al. are most often used. In order to obtain more uniformity in CRPS diagnosis, generally accepted criteria are necessary. The IASP criteria have been criticized for their lack of specificity, leading to overdiagnosis and heterogeneous patient populations. Although the Dutch criteria appear to be more specific, they are not accepted internationally. Previous research has shown that signs and symptoms of CRPS can be categorized into four independent groups. Revised diagnostic criteria have been proposed based on these four groups (in the "Budapest" conference), which appear to have a better balance of diagnostic sensitivity and specificity than the IASP criteria. The formal adoption by the IASP of these revised criteria necessitates further validation.

The current proposal concerns aims to determine the reliability of the proposed new diagnostic criteria for CRPS. The objective is to enrol 50 CRPS patients for determining the interrater reliability of the diagnostic set. Primary outcome measures are occurrence of certain signs and symptoms.

Secondary outcome measures include pain, quality of life and neurophysiological parameters. Time investment for patients is approximately 2 hours. There are no risks involved for participants

Study objective

To determine the reliability of the newly proposed diagnostic criteria.

Study design

Observational design

Study burden and risks

In total the investigations will take maximally 2 hours per patient. No risks are involved in participating.

Contacts

Public

Vrije Universiteit Medisch Centrum

Boelelaan 1117
1007 MB Amsterdam
Nederland

Scientific

Vrije Universiteit Medisch Centrum

Boelelaan 1117
1007 MB Amsterdam
Nederland

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 or older meeting the current criteria for CRPS

Exclusion criteria

Patients with other complaints or syndromes that could otherwise account for the degree of pain and dysfunction

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2008

Enrollment: 50

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL22690.029.08