The cross-sectional validity of three measurement instruments for central sensitization

Published: 24-12-2014
Last updated: 22-04-2024

The primary aim of the study is to establish the cross-sectional validity of three different measurement instruments for central sensitization, including the Dutch Central Sensitization Inventory and two test to measure pain inhibition: heterotopic...

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

Summary

ID

NL-OMON44607

Source
ToetsingOnline

Brief title
Measuring central sensitization

Condition

- Other condition

Synonym
chronic painsyndrome, somatization

Health condition

diverse aandoeningen (b.v. fibromyalgie, whiplash, vermoeidheidssyndroom) waarbij centrale sensitisatie vaak aanwezig is

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Central sensitization, Measurements instruments, Validation

Outcome measures

Primary outcome

Outcomes of the CSI and pain pressure thresholds [PPT]

Secondary outcome

N.A.

Study description

Background summary

Many patients with chronic pain show features of central sensitization. Central sensitization, characterized by generalized hypersensitivity of the somatosensory system, is due to a dominance of the facilitatory system over the inhibitory system. The presence of central sensitisation is a negative prognositc factor and might be an indication of a poor response to physical therapies. Currently, an international consensus definition or clinical criteria for central sensitization is essentially lacking.

Study objective

The primary aim of the study is to establish the cross-sectional validity of three different measurement instruments for central sensitization, including the Dutch Central Sensitization Inventory and two test to measure pain inhibition: heterotopic noxious conditioning stimulation test and a submaximal exercise test
The secondary aim is to compare the results on the three different measurement instruments for central sensitizationtest between persons with fibromyalgia and persons without complaints.
The tertiare aim is to establish the optimal cutoff pont for the Central Sensitization Inventory to identify persons with central sensitization.

Study design

All patients will sign an informed consent. In one session the patient will complete the Dutch Central Sensitization Inventory and two tests, a heterotopic noxious conditioning stimulation test and a submaximal exercise test. Before the tests pain pressure thresholds (PPT) will be measured at three different sites; on the proximal third of the calf, at the upper trapezius muscle (pars descendens) midway between the seventh cervical vertebra and the tip of the acromion, and on the middle dorsal side of the third digit. The subject need to indicate when the pressure is starting to feel painfull. At that moment, the achieved pressure in kilogram/cm2 (kg/cm2) will be noted as the PPT. Each measurement will be conducted twice on both the left and right side. Of these 2 measurements per site a mean value will be calculated. PPT will be measured with a manual analog Fisher algometer (Force Dial model FDK, Wagner Instruments).
The heterotopic noxious conditioning stimulation test: The participant sit on a chair. The non-dominant hand is submersed up to 10cm above the wrist in hot noxious water (45,5°C) for 6 minutes. After 2 minutes of submersion of the hand, PPTs are measured at the three different sites of the dominant side. Two minutes after the conditioning stimulus is removed, PPT measurements are performed again on the dominant side.
The submaximal exercise test: For this test we use the Aerobic Power Index Test. This test is performed on a bicycle ergometer, starting at 25 Watt. After 5 min. warming-up the resistance is gradually increased by 25 Watt/minute until 75% of the age predicted maximal heart rate (220 minus age) is achieved.Two minutes after the test, PPT measurements are performed again on 3 sites of the dominant and non-dominant side (6 locations).
The order of the tests will be allocated by randomisation for each participant.

Study burden and risks

Patients who are central sensitizied can show signs of dizziness, headache, fatigue or nausea due to the test protocol. However, the protocol ensures that the duration of the tests will be kept low (<10 minutes), thus avoiding extreme fatigue or deregulation of the autonome system. Besides, test can be cancelled at any time by the researcher or patient. Therefore, we do not expect severe complaints due to the test protocol or complaints lasting longer than 24 hour. The level of pain, nausea and dizziness will be recorded before the two tests, for every patient.

Contacts

Public
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815JD
NL
Scientific
Medisch Centrum Alkmaar

Wilhelminalaan 12
Alkmaar 1815JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group 1 (n<=50): Persons with fibromyalgia (diagnostic criteria 1990)
Group 2 (n<=20): Persons without complaints (no pain); the absence of disabling pain the past 2 weeks, no use of medication

Exclusion criteria

- neuropathic pain
- severe diseases like cancer
- pregnant
- cardiovascular diseases
- neurological diseases
- diabetes.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2015
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2014
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	10-08-2017
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL50214.094.14