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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26154

Source
NTR

Health condition

Centrale sensitization in patients with fibromyalgia

Sponsors and support

Primary sponsor: Medical Centre Alkmaar, rehabilitation department
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Outcomes of the CSI and pain pressure thresholds [PPT]

Secondary outcome

NA

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.

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 (CSI) 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.

The study aims at enrolling 100 patients form the rehabilitation clinic and the reumatology clinic of the Medical Centre Alkmaar; 50 patients with fibromyalgia (a typical central sensitization image) and 50 healthy pain-free control subjects.

The results are outcomes of the CSI and pain pressure thresholds [PPT]

Study objective

The correlations between the three measurement instruments are moderate (r = 0,41 to 0,60).

Study design

NA

Intervention

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.

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Eligibility criteria

Inclusion criteria

Group 1 (n=50): Persons with fibromyalgia (diagnostic criteria 1990) Group 2 (n=50): 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
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2015
Enrollment:	100
Type:	Unknown

Ethics review

Positive opinion

Date:	02-04-2015
Application type:	First submission

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
NTR-new	NL4984
NTR-old	NTR5130
Other	: METC: M014-017

Study results

Summary results
not yet