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

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26154

Bron
NTR

Aandoening

Centrale sensitization in patients with fibromyalgia

Ondersteuning

Primaire sponsor: Medical Centre Alkmaar, rehabilitation department
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Outcomes of the CSI and pain pressure thresholds [PPT]

Toelichting onderzoek

Achtergrond van het onderzoek

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]

Doel van het onderzoek

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

Onderzoeksopzet

NA

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	100
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	02-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4984
NTR-old	NTR5130
Ander register	: METC: M014-017

Resultaten

Samenvatting resultaten
not yet