The role of attention in endogenous pain control

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35822

Source
ToetsingOnline

Brief title
Role of attention in pain control

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
fibromyalgia; muscle, joint or bone

Research involving
Human

Sponsors and support

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

Intervention

Keyword: attention, Conditioned Pain Modulation, Diffuse Noxious Inhibitory Controls, fibromyalgia, pain

Outcome measures

Primary outcome

The primary study parameter is the effect of attentional modulation on CPM

efficacy in patients with fibromyalgia compared to healthy controls.

Secondary outcome

Secondary parameters are: 1) attentional task performance in patients with

fibromyalgia versus healthy controls, 2) associations between CPM efficacy and

cognitive inhibition, and 3) sex differences in CPM efficacy and attentional

effects in fibromylagia versus healthy controls.

Study description

Background summary

Conditioned pain modulation (CPM), the phenomenon that pain inhibits pain, reflects a central pain modulatory system that relies on spinal and supraspinal mechanisms. Previous studies have shown that fibromyalgia patients have deficits in CPM compared to healthy controls. It has been argued that the CPM effect can be partly explained by attentional manipulation as application of a second painful stimulus may distract attention from the first painful stimulus. It remains however unclear what role attention plays in endogenous modulation of pain, specifically in fibromyalgia.

Study objective

The primary objective of this study is to examine whether distraction interferes with CPM modulation differently in patients with fibromyalgia compared to healthy controls. Secondary objectives include assessing whether patients have a general deficit in executive attentional function, if CPM magnitude is related to cognitive inhibition, and how sex differences may explain CPM magnitude differences in fibromyalgia patients compared to healthy

controls.

Study design

This study is a monocenter randomized repeated measures study. Subjects will be screened for study participation and informed consent will be signed. Procedures will be explained and questionnaires will be filled out. Subjects will not be informed about the actual study hypotheses or on the pain intensity levels applied beforehand to avoid expectancy influencing the data. This is a common procedure in this type of research. Painful stimulation levels will be individually determined and attentional tasks including the attention network test and the Stroop color-word test will be performed. Also, a memory task and a tapping task will be performed. Four experimental sessions will be completed semi-randomly: 1) painful test stimulus alone, 2) test stimulus in combination with a conditioning stimulus (CPM), 3) test stimulus in combination with a Stroop distraction task, 4) CPM in combination with a Stroop distraction task. Difference scores in pain ratings of test stimuli alone or in combination with another stimulus will be determined. As a control, painful stimulation will be repeated after experimental testing to verify that no shifts in baseline measures occurred and subjects will be debriefed.

Study burden and risks

Participants will complete one visit of approximately 2 hours at the Pain Clinic of the UMC Utrecht. Risks associated with study participation are minimal. The equipment used to induce pain is safe and commonly used in clinical practice. There will be no direct benefit to participants. The present study will provide new insights in the mechanisms of endogenous pain modulation and will demonstrate what role attention plays in CPM efficacy. Participants will be able to terminate study participation at any time, for any reason.

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

Patients will have the diagnosis of primary fibromyalgia according to the American College of Rheumatology (ACR) classification criteria. Control participants will be matched on age and educational level to fibromyalgia patients and will be healthy and pain-free as determined by a general health questionnaire, and not take any psychoactive medication or analgesics. All subjects will be adults over the age of 18 years old and speak Dutch fluently.

Exclusion criteria

The inability to give informed consent, a serious neurological or psychiatric condition besides fibromyalgia, current participation in another research protocol that could interfere or influence the outcome measures of the present study , current use of sedative psychotropic or analgesic drugs (e.g., benzodiazepine, antiepileptics, barbiturates and opioids) except amitriptyline in low dosages (<50 mg/day), or when there is any serious injury to the body regions to be tested as reported by the research participant.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-06-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL36078.041.11