Conditioned pain modulation in oarsmen compared to non-athletic controls - the ROW study

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The aim of this study is to assess differences in the endogenous pain modulation paradigm in older and younger subjects, with and without an intensified sports regimen (ie. oarsmen).

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

Summary

ID

NL-OMON47300

Source
ToetsingOnline

Brief title
ROW

Condition

- Other condition

Synonym
pain modulation

Health condition

pijnverwerking

Research involving
Human

Sponsors and support

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

Intervention

Keyword: endogenous pain modulation, rowers

Outcome measures

Primary outcome

The CPM magnitude will be calculated by averaging the different tests, and

comparing peak VAS values or area-under-the-curves to assess time- and

conditioning-stimulus-related changes between groups.

Secondary outcome

na

Study description

Background summary

Pain is common phenomenon in athletes. In addition to sports-related injuries, fanatic sportsmen even continue to exercise while they suffer from severe injury. On the other hand, physical activity is part of most pain treatment programs. There is consistent evidence that physical activity activates generalized endogenous pain modulation mechanisms, such as exercise-induced or stress-induced hypoalgesia. These phenomena involve reduced pain perception during or shortly after intense stress or exercise.1
In contrast to the acute effects of exercise, there is controversial evidence of the effect of chronic exercise on pain perception or pain modulation in athletes. Two recent studies addressed the more long-term alterations in endogenous pain modulation in endurance athletes. In the first study, it was shown that triathletes had a greater conditioned pain modulation (CPM) magnitude,2 which is an experimental measure of endogenous pain inhibition, whereas the second study demonstrated reduced capability of endurance athletes to engage CPM pathways.3 The latter was possibly explained by exhaustion of the endogenous pain inhibitory pathways due to chronic overstressing. The discrepancies between the two study outcomes may be related to the type of

athletes, methodological or analytical differences.
A second factor known to affect the CPM magnitude is ageing. There is increasing evidence in literature that older adults have decreased CPM engagement. This phenomenon is thought to contribute to the reduced ability of older adults to cope with severe persistent pain states and to the greater prevalence of pain in older age.4-6
Oarsmen are competitive rowers with high frequency training schedules, sometimes up to 6 training exercises per week. Training and competitions induce a considerable amount of stress and pain endurance over several hours per day. Rowers frequently suffer from rib injuries and low back pain. Competitive rowers and experimental pain tests have been the topic of one publication, where pain thresholds and pain tolerances in 20 male rowers in training and 20 male controls were assessed.7 Pain tolerances were higher for competitive rowers,7 indicating that pain modulation may be altered in these athletes. Competitive rowing athletes provide a unique opportunity to study the effect of chronic physical exercise on the endogenous pain modulation system. We have the opportunity to test *young* and *old* oarsmen, whereby we can assess the effect of intensified sports and ageing on CPM magnitude.

Study objective

The aim of this study is to assess differences in the endogenous pain modulation paradigm in older and younger subjects, with and without an intensified sports regimen (ie. oarsmen).

Study design

Heat pain model. A thermal stimulus will be applied on the volar side of the forearm using the thermal probe (a 3 X 3 cm thermode) of the Pathway or Q-sense devices (Medoc Ltd, Ramat Yishai, Israel). These are computer-controlled devices capable of generating highly reproducible thermal stimuli. The Visual Analogue Scale (VAS) will be measured electronically using a slide potentiometer that can be moved from the left (0 or no pain) to the right (10 cm or most intense pain imaginable).
Electrical pain model. We will use the Computer-Interfaced Current Stimulator (CICS) that was developed at LUMC by R. Sloos (Technical Department) and E. Olofsen (Dept. of Anesthesiology). Transcutaneous electrical stimulation will applied to the skin via two surface electrodes (Red Dot; 3M, London, Ontario). The electrodes are applied on the proximal forearm at a mid-position between the volar and dorsal aspects (avoiding stimulation above a main nerve trunk). In this study we will use fixed stimuli and will use the numerical rating scale (NRS) to score the electrical pain intensity. We will use a stimulus that will cause an NRS score of 6.
Cold pain. Cold pain will be applied to the foot of the patient. For baseline measurements, the foot of the patient will be immersed in a cold water bath ranging from 6-12 oC. The temperature that evokes an NRS of 3 will be used in

the remainder of the study.
Baseline measurements. Prior to the test sequence, the patients will be familiarized with the experimental set up. The procedure will be explained to them in detail. Next, a set of test stimuli is applied to obtain setting for fixed pain scores of 6 for heat stimuli and for electrical stimulation. To that end, multiple in strength increasing stimuli are applied. For heat pain the ramp starts at 38 oC and the heat will increase to 43 oC and plateau for 10 sec before returning to baseline. The patient will score the pain using the VAS. When the pain rating is < 6, a next stimulus will be applied (from 38 to 44 oC). Again, when the pain score is < 6 cm next stimulus will be applied. The first temperature at which the pain score is 6 or greater will be used in the study.
For the electrical pain protocol a similar approach is applied. Each stimulus is rated verbally, and the first stimulus that gives an NRS of 6 or greater will be used in the study. Steps start at 0.5 mA and will increase by 0.5 mA/sec.
Conditioned Pain Modulation (CPM). The test stimulus is made up of a heat stimulus to the volar side of the non-dominant forearm and is applied using the Medoc 3 x 3 cm thermode using the Q-sense or Pathway devices. The temperature of the thermode is maintained at 32 oC for 20 seconds followed by a temperature that gives an NRS of 6 (this stimulus is defined at baseline). The stimulus is maintained for 10 seconds. The patients will score pain perception using the electronic VAS system. Then the thermode is removed and 3 electrical stimuli (again aimed at NRS 6) are applied with a 1 s interval. The stimuli are applied to the non-dominant arm. The patient will verbally rate each of the stimuli on NRS.
First the test stimuli will be applied alone (ie. first pain). After a 10 min break the test stimulus will be applied together with the second pain stimulus, the conditioning stimulus. The conditioning stimulus is a cold water stimulus to the foot (NRS 3), contralateral of the dominant arm. The foot will be immersed (t = 0 s), and the test sequence (heat and electrical pain) will be started 20 seconds after foot immersion. See also figure 1. The CPM test will take about 15 min and will be repeated three times per test with a 5 minute rest period between tests (total test duration 40 minutes).

Study burden and risks

For this study, volunteers will be recruited. The study involves sensory testing models with short pain stimuli. The estimated risk for the participant is therefore minimal. The potential damage that could be inflicted onto the subjects is also mild, as these tests are known to be well tolerated. The risk for the subjects in our opinion is therefore negligible.

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

Healthy male volunteers. The control cohorts (group 3 and 4 as listed above) is allowed to perform light to moderate exercise.

Exclusion criteria

At least one of the following criteria:
- Unable to understand study information or give oral and written informed consent;
- Obesity (BMI > 30 kg/m2);
- Pregnancy;
- History of chronic alcohol or illicit drug use;
- History of illness, condition or medication use that, in the opinion of the investigator, might

interfere with optimal participation, or could confound the results of the study.

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-07-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	21-07-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	23-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL57937.058.16

Study results

Date completed: 05-12-2019

Actual enrolment: 30