The relation between cerebral blood flow, pain attenuation and autonomic parameters in rest, during and after exercise in patients with the chronic fatigue syndrome.

Published: 19-03-2014
Last updated: 24-04-2024

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

Summary

ID

NL-OMON40186

Source
ToetsingOnline

Brief title
Cerebral blood flow, pain and chronic fatigue syndrome

Condition

- Other condition

Synonym
chronic fatigue syndrome, myalgic encephalitis

Health condition

chronisch vermoeidheidssyndroom

Research involving
Human

Sponsors and support

Primary sponsor: ZBC Stichting Cardiozorg
Source(s) of monetary or material Support: het onderzoek wordt NIET gefinancierd

Intervention

Keyword: cerebral blood flow, chronic fatigue syndrome, exercise, pain attenuation

Outcome measures

Primary outcome

The primary outcome of this study is the relationship between decreased

cerebral blood flow during exercise and increased pain sensation after

exercise.

Secondary outcome

Secondary Outcomes:

- Cerebral blood flow before and after tilt table testing

- Comparison of CBF changes between exercise and tilt table testing

- Comparison of CBF changes between patients and healthy subjects

- Comparison of PPT between patients and healthy subjects

- Comparison of peak oxygen consumption between patients and healthy subjects

- Relation of CBF and an increase in oxygen consumption during exercise.

- Comparison of Vasalva maneuver measurements between patients and healthy

subjects

- Comparison of questionnaires between patients and healthy subjects.

Study description

Background summary

Besides the characteristic fatigue, patients with Chronic Fatigue Syndrome (CFS) often suffer from chronic widespread and persistent pain. A population-based study revealed that 94 % of the persons diagnosed with CFS report muscle pain, and 84 % report joint pain.
Previous research has shown that altered central pain processing and altered pain inhibition mechanismens play a role in the increased pain perception of CFS patients. It has been shown also that the normal inhibition of pain by exercise is diminished or absent in CFS patients.
The underlying mechanism for these altered pain sensations in CFS is mostly unclear. In fibromyalgia patients a relation with the impaired autonomic functions has been demonstrated, mainly by measuring heart rate variability (HRV). HRV data in CFS patients are limited and data are inconsistent. The relation of impaired autonomic function and altered pain sensation in CFS patients is unknown.
Heart rate variabiliyt and baroreflex sensiivity seem to play a role in pain sensation and cardiovascular responses to pain.
To the best of our knowledge, studies examining the relation between ANS and pain in CFS are lacking. Likewise, studies investigating CBF in CFS are rare. Also in healthy controls, studies examining exercise induced analgesia in relation to autonomic function and CBF in response to exercise are lacking. On the other hand, it has been demonstrated that the baroreflex sensitivity is decreased in CFS patient. But also the relation between the decrease of the baroreflex sensitivity and altered pain perception is not known.
Moreover it is unknown, also in healthy volunteers, to which magnitude the baroreflex and the stress of the exercise indipendently contribute to the decreased pain sensation after exercise. Similar, this is also unknown in CFS patients.
Finally, there are limited studies which investigated cerebral blood flow at rest in CFS. There are no studies of the changes in cerebral blood flow during exercise and therefore also studies are lacking which related the exercise-induced analgesia with autonomic function tests and with changes in cerebral blood flow during and after exercise.

Study objective

Therefore the aim of the study is to determine the relation between cerebral blood flow during and after exercise, the altered pain sensation after exercise and autonomic functions (HRV and baroreflex sensitivity) in response to exercise in patients with CFS. These relations will be compared to those of healthy controls. Furthermore, the altered pain response to exercise will be compared to that of an non exercise test: tilt table test. Finally, the changes of cerebral blood flow during a Valsalva manoeuvre will be determined as well

as the effect of the Valsalva manoeuver on pain thresholds.

Study design

Participants are randomized to either the submaximal bicycle exercise test, or to the emotional stressor. Prior to the first test, questionnaires will be filled in to make an inventarisation of the pain, physical condition, complaints of fatigue and general well being. After measuring pain thresholds, a Valsalva manoeuvre will be performed, cerebral blood flow will be measured and the HRV and baroreflex data will be recorded. Thereafter patients will be randomized to either the emotional stressor or to the exercise. During the exercise test oxygen uptake (VO2) will be measured: spiro-ergometry.The week thereafter the other test will be performed. During both tests cerebral blood flow will be measured and autonomic function data collected and after the test pain thresholds will be measured.

Study burden and risks

As already answered in question E9 risks are low as is the burden of participation.

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

CFS patients within the range of 18-65 years of age, who are diagnosed according to the Centre of Disease Control criteria
Before being asked to participate to the study, the International Physical Questionnaire *short form, Dutch version- will be sent to potential candidates. Only those with categorical score: *low* will be asked to participate.

Exclusion criteria

- Pregnancy or being postnatal within 1 year.
- - The current use of opioid medication.
- BMI >30.
- Unable to perform a maximal exercise test.
- Diabetes mellitus.
- Medical condition leading to chronic pain in sedentary controls.
- Suspicion of ischaemic complaints, regional wall motion abnormality or moderate to severe valvular disease.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	06-10-2014
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2014
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	23-10-2014
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL44183.048.13

Study results

Date completed:	01-10-2018
Actual enrolment:	650