Experience and report of non-specific symptoms in chronic fatigue syndrome

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To compare an unexplained chronic fatigue group and a healthy control group on: 1) immune parameters (hs-CRP), 2) several subjective (self report) measures of non-specific symptoms of immune activity, 3) several objective measures of non-specific...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34662

Source
ToetsingOnline

Brief title
Non-specific symptoms of chronic fatigue syndrome

Condition

- Other condition

Synonym
chronic fatigue syndrome

Health condition

functionele syndromen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: chronic fatigue, CRP, symptoms

Outcome measures

Primary outcome

Primary study parameters are: blood plasma CRP-concentrations; self report of negative mood, fatigue, pain complaints and cognitive complaints; pressure pain parameters; and mental effort during a cognitive task.

Secondary outcome

Secondary study parameters are Indoleamine 2,3-dioxygenase-mRNA expression and score on a pain catastrophizing questionnaire.

Study description

Background summary

The recent study is based on the assumption that medically unexplained complaints are due to an increased sensitivity of the brain to signals from the immune system (i.c. cytokines). The study will focus specifically on this role of central sensitivity for cytokines in chronic unexplained fatigue. Assessment of immune activity in chronic fatigue syndrome (CFS) has not led to consistent findings in the past. More recent studies, however, which used a more sensitive immunological test (high-sensitivity C-reactive protein (hs-CRP) concentrations), did find differences between chronic fatigued and healthy individuals. This positive development gives us the opportunity to further study the role of immune deviations in relation to CFS complaints. This research on non-specific symptoms of immune activity will focus on self reported symptoms on the one hand, and more objective measures like pain sensitivity and mental effort during tasks on the other hand.

Study objective

To compare an unexplained chronic fatigue group and a healthy control group on: 1) immune parameters (hs-CRP), 2) several subjective (self report) measures of non-specific symptoms of immune activity, 3) several objective measures of non-specific symptoms.

To assess dose-reponse relationships between hs-CRP and subjective and objective non-specific symptoms within the chronic fatigue group.

Study design

An observational study with two groups: a group with unexplained chronic fatigue and a healthy control group.

Study burden and risks

Participants are asked to travel to Utrecht on two occasions: once for the screening appointment (1 hour), and once for the test day (3 hours).
The test day consists out of four questionnaires, one computer task and one pain sensitivity assessment. During this day, several breaks are scheduled to prevent the study from causing further fatigue in the chronic fatigued participants. The questionnaires and tests used in this study have been used before in studies with chronic fatigue participants.

During the test day, a blood sample will be obtained through vena puncture. The vena puncture can lead to a bruise at the place of the puncture. In rare cases, the puncture can lead to an infection at the place of the puncture.

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

Female, non-smoking, age between 20 and 60 years. No medical or psychiatric disorder. Specific for patientgroup: unexplained chronic fatigue lasting more than 6 months.

Exclusion criteria

Indication or diagnosis of any medical or psychiatric disorder. Use of systemic medication. Drugs use in month prior to study. Alcohol abuse in month prior to study. Primary sleep disorder that can account for the fatigue complaints. Pregnancy during or in three months before the study. Occurrence of an infection in the week prior to the study. Experience from earlier research shows that about 50 % of potential participants in the chronic fatigue group will be excluded due to use of systemic medication.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	72
Type:	Anticipated

Ethics review

Not approved

Date:	01-03-2010
Application type:	First submission
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	NL30479.041.09