Sleep in Dutch Veterans with Deployment Related Post Traumatic Stress Disorder; Analyses of Polysomnography and HPA-axis Parameters

Published: 13-11-2007
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The aim of this study is to examine arousals in PTSD, and to investigate the correlation of arousals with nocturnal excretion of hormones of the HPA-axis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON31378

Source
ToetsingOnline

Brief title
Sleep in Deployment Related Post Traumatic Stress Disorder

Condition

- Sleep disturbances (incl subtypes)
- Anxiety disorders and symptoms

Synonym
psychological trauma, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: Cortisol, Polysomnography, Post traumatic stress disorder, Sleep

Outcome measures

Primary outcome

The primary outcome measures are the number of arousals and nocturnal exctrion of cortisol.

Secondary outcome

Secondary objectives are

1. Other PSG parameters

2. Nocturnal excretion of catecholamines and hormones of the HPA axis (other than cortisol)

3. Correlations of plasma concentration of catecholamines and hormones of the HPA axis with number of arousals and other PSG parameters

4. Correlation of subjective sleep complaints with number of awakenings and other PSG parameters

5. Correlation of objective and subjective sleep quality with temperament, general psychological and somatic well being, according to VTCI, SCL-90 and CIS

6. Correlation of performance on memory task (delayed recall) and number of arousals

Study description

Background summary

Posttraumatic stress disorder (PTSD) is an often chronic and disabling disorder. Sleep complaints are reported in 70 % of the PTSD patients and may be caused by altered and hypothalamo- pituitary- adrenal (HPA) axis activity in PTSD.

Study objective

The aim of this study is to examine arousals in PTSD, and to investigate the correlation of arousals with nocturnal excretion of hormones of the HPA-axis.

Study design

After screening for sleep disorders, aneamia and other relevant medical conditions, the subjects will sleep for two nights at the sleep unit of the Military Mental Health Care (MGGZ). During the second night polysomnographic recordings will be obtained, and multiple blood samples will be obtained through an intravenous catheter. In addition, subjective sleep quality will be measured with a self-administered sleep questionnaire (Pittsburgh Sleep Quality Index), and a sleep calendar. Psychological en physical well being will be assessed with CIS, and SCL-90. Temperament will be assessed with the VTCI. On the second night a memory task (15 words test) and a sustained attention test (Bourdon Wiersma Test) will be performed. Furthermore, a short form of the WAIS III will be performed to assess IQ. In the morning delayed recall of the 15 words will be assessed.

Study burden and risks

1. Three nights PSG in sleep laboratory
The sleep registrations at Kempenhaeghe will be done at friday nights, when the ward is available for subjects of this study only.
The sleep lab of the MGGZ is in a quiet part of the MGGZ where no patients are admitted.
2. Intravenous cannulation
There is a very small risk of infection and bleeding associated with intravenous cannulation, which is prevented by proper techniques and skilled personnel.
3. Blood sampling. A maximum amount of 250 ml will be drawn over a time period of 12 hours. Patients with anaemia will not be allowed in this protocol.
4. Psychological testing can lead to a temporary increase of symptoms. This will be explained to all participants beforehand. Participants can contact the investigators and the clinic of the MGGZ when complaints will not diminish.

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

- Age between 18 - 55
- Male
- Veterans or active military personnel
- History of deployment (PTSD and trauma controls)
- CAPS > 50 (PTSD patients)

Exclusion criteria

- Substance or alcohol dependence within the past six months
- History of psychiatric disorders (trauma controls, healthy controls)
- CAPS > 18 (trauma controls)

- Significant psychological trauma in the past (healthy controls)
- Any clinically significant abnormal finding during medical history or physical examination
- Anemia (hemoglobin < 8.5 mmol/l)
- Sleep disturbed breathing (SDB) or periodic limb movement disorder (PLMD)
- Use of any psychotropic medication.
- Chronic benzodiazepine use. Benzodiazepine use on demand will be stopped at least two weeks before the study nights. A subject can only participate if no rebound effects after cessation of benzodiazepines are reported.

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:	Recruitment stopped
Start date (anticipated):	14-11-2007
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-01-2008
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-02-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2009
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	NL18585.041.07