# Nocturnal excretion of cortisol, CRH and catecholamines, and their relation to sleep EEG in deployment related posttraumatic stress disorder (PTSD)

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The aim of this study is to examine if an increased number of awakenings in PTSD is PTSD dependent or trauma dependent. Furthermore, the purpose of the study is to examine if the nocturnal excretion of cortisol is increased.

| Ethical review        | Not approved                       |
|-----------------------|------------------------------------|
| Status                | Will not start                     |
| Health condition type | Sleep disturbances (incl subtypes) |
| Study type            | Observational invasive             |

# Summary

### ID

NL-OMON30459

**Source** ToetsingOnline

**Brief title** sleependocrinology in PTSD

# Condition

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

#### Synonym

posttraumatic stress disorder, trauma

**Research involving** 

Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** Ministerie van Defensie

### Intervention

Keyword: cortisol, noradrenalin, polysomnography, PTSD

### **Outcome measures**

#### **Primary outcome**

The primary outcome measure is number of awakenings of plasma cortisol

concentrations.

#### Secondary outcome

Secondary objectives are

- 1. Other PSG parameters
- 2. Nocturnal excretion of catecholamines and hormones of the HPA axis in
- 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

general

psychological and somatic well being, according to \*Symptom

Checklist -

- 90\* (SCL-90) and \*Checklist Individuele Spankracht\* (CIS).
- 6. Correlation of sleep endocrinology with temperament and personality,
- as measured by \*Temperament and Character Inventory\*.

controls

# **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. Polysomnography (PSG) studies in PTSD have reported on an altered arousability during the night. In these studies arousability has not yet been compared with a trauma control group and non-trauma control group. Sleep disturbances in PTSD may be correlated with altered noradrenergic activity and hypothalamus- pituitary- adrenal axis (HPA) dysfunction. Alterations in neuro-endocrine function after deployment have been found in veterans without PTSD as well.

#### **Study objective**

The aim of this study is to examine if an increased number of awakenings in PTSD is PTSD dependent or trauma dependent. Furthermore, the purpose of the study is to examine if the nocturnal excretion of cortisol is increased.

### 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; Militaire Geestelijke Gezondheidszorg). 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.

#### Study burden and risks

Risks and burden for patients includes: admission sleep laboratorium, intravenous cannulation, psychological testing

#### 1. Admission

During the admission at the clinic, the contact with patients will be minimised as the participants will stay at a separate part (research unit) of the clinic.

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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, 250 ml drawn blood can give some dizziness in patients with mild anaemia. Therefore, patients with anaemia will be excluded.

4. Psychological testing can lead to a temporary increase of symptomes. This will be explainted to all participants. Participants can contact the investigators and the clinic of the MGGZ in case of emergencies.

# 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**

male, age 18-65, CAPS > 50 (patients)

### **Exclusion criteria**

substance /alcoholabuse within 6 months psychotrophic medication chronical benzodiazepin use History of psychiatric disorder (controls), CAPS > 18 (contorls)

# 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:         | 60             |
| Туре:               | Anticipated    |

# **Ethics review**

| Not approved       |   |
|--------------------|---|
| Date:              | 19-06-2007  |
| Application type:  | First submission                                    |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

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# **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** CCMO **ID** NL16226.041.07