# Prazosin in the pharmacological treatment of sleep disturbances in post traumatic stress disorder, a placebo-controlled study using polysomnography

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The aim of this study is to evaluate the efficacy of prazosin for the treatment of PTSD related sleep disturbances, and to evaluate response with objective and subjective parameters.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Sleep disturbances (incl subtypes) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33617

**Source**
ToetsingOnline

**Brief title**
prazosin in the treatment of PTSD related sleep disturbances

### Condition

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

**Synonym**
posttraumtic stress disorder, psychotrauma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Militaire Geestelijke Gezondheidszorg

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

## Intervention

**Keyword:** placebo controlled, prazosin, PTSD, sleep

## Outcome measures

### Primary outcome

1) A decrease in number of awakenings after treatment, as measured with PSG.

2) Subjective sleep quality using self reported questionnaires (sleep calendar, Pittsburgh Sleep Quality Index).

### Secondary outcome

1) Changes of other PSG parameters after treatment (wake after sleep onset (WASO), sleep latency (SL), and total sleep time (TST), percentage rapid eye movement (REM) sleep, percentage non REM (NREM) 2, percentage NREM 3+ 4, delta-activity during NREM 3 + 4, mean heart rate during each sleep stage):

2) Correlation between improvement on subjective reports and the change in number of awakenings.

# Study description

### Background summary

Posttraumatic stress disorder (PTSD) is an often chronic and disabling disorder. Nightmares have been acknowledged as the hallmark of PTSD. Overall, sleep complaints affect about 70% of PTSD patients.
The majority of PTSD patients is treated with a selective serotonin reuptake inhibitor (SSRI). Although SSRIs are effective for most PTSD symptoms, sleep disturbances are generally therapy resistant to SSRIs.
Placebo controlled studies in PTSD have shown that prazosin, an alpha 1 adrenoceptor blocking agent, was effective in the treatment of nightmares and insomnia after 8 weeks of treatment. Only subjective sleep quality was measured to evaluate the effect of prazosin in this study.

In spite of the disturbed subjectieve sleep quality, a relatively normal (macro)sleep architecture is seen with controlled studies using polysomnography (PSG). However, PSG studies did identify disturbed sleep patterns such as a higher number of (micro)awakenings.
Evaluating the efficacy of prazosin with both subjective and objective parameters may provide more insights in the underlying mechnisms of sleep complaints in PTSD.

## Study objective

The aim of this study is to evaluate the efficacy of prazosin for the treatment of PTSD related sleep disturbances, and to evaluate response with objective and subjective parameters.

## Study design

This study is a double-blind, placebo-controlled randomized trial with prazosin or placebo as add-on medication to standard treatment with a SSRI. This trial will be conducted at the research centre of the MGGZ in collaboration with the UMC Utrecht and Kempenhaghe, Centre for Sleep and Wake Disorders and Centrum 45. A patient information form will be provided and written informed consent will be obtained from all subjects prior to entry to the trial.
After screening for psychiatric co-morbidity and other relevant medical conditions, the subjects will be randomized into the prazosin or placebo group. Clinician and patient are blind for the treatment status. Patients will be treated for 8 weeks. Polysomnography will be performed at baseline and endpoint of the treatment phase. Additional visits are planned at week 3, 5 and 7 for evaluating side effects and blood pressure and, when needed, for adjusting the dosage.

## Intervention

Treatment with prazosin or placebo for 8 weeks.

## Study burden and risks

1. Side effects after administration of prazosin.
To reduce risks:
*Slow titration in first four weeks
*When orthostatic hypotension occurs as a side effect, patients will be advised to avoid situations that can cause hypotension in the first weeks, like suddenly rising from a chair or bed. When these symptoms occur patients are advised to lie down until symptoms subside.
*Patients can call physician on call in case of side effects.

2. PSG recordings (Participants of MGGZ and UMC Utrecht).

Subjects will sleep with PSG equipment for a total of 4 nights.
To minimize the burden we will use ambulantory equipment (2 nights before and 2 nights at the end of the treatment phase), so the participants can sleep at home. Electrodes will be applied at the MGGZ or, and removed after the second night at the MGGZ. Or the researchers go to the homes of the participants to apply, and remove, the electrodes.

## Contacts

**Public**
Militaire Geestelijke Gezondheidszorg

Heidelberglaan 100
3584 CX Utrecht
NL
**Scientific**
Militaire Geestelijke Gezondheidszorg

Heidelberglaan 100
3584 CX Utrecht
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

Age between 18 - 65
Veterans, active military personnel, refugees, or civilians with psychotrauma
Subjects have to meet DSM-IV criteria for PTSD, as measured by SCID, with a CAPS score of > 50

PSQI scores of > 5

### Exclusion criteria

Substance or alcohol abuse/ dependence within the past six months
Major systemic or neurological diseases
Orthostatic hypotension before treatment
History of micturition syncope
History of allergic reaction to prazosin
Use of psychotropic medication with apha 1 antagonizing properties
Use of antihypertensive agents
Start psychotherapy in the 6 weeks proceeding the trial.

## Study design

### Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 08-01-2009 |
| Enrollment: | 50 |
| Type: | Actual |

### Medical products/devices used

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| Product type: | Medicine |
| Brand name: | prazosin |
| Generic name: | prazosin |

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| Registration: | Yes - NL outside intended use |

## Ethics review

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| Approved WMO Date: | 13-10-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 16-12-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 15-09-2009 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 06-10-2009 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 16-11-2009 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 11-02-2010 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 17-03-2010 |
| 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 |
|---|---|
| EudraCT | EUCTR2007-000030-39-NL |
| CCMO | NL16434.041.07 |