An open label study with objective sleepregistration on the effects of Doxazosin as treatment for PTSD, especially for sleep disturbance

Published: 30-08-2012
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To evaluate the effect on sleep and ptsd of the drug Doxazosin Retard in patients with PTSD who also have sleep problems.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON37075

Source
ToetsingOnline

Brief title
Doxazosin for PTSD With sleepregistration (DoPS).

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic stress disorder; psychotrauma

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: Het wordt door ParnassiaBavoGroep zelf

gefinancierd.

Intervention

Keyword: Doxazosin, Posttraumatic Stress Disorder, Sleepdisorders

Outcome measures

Primary outcome

- Items and sum of items measuring sleep quality of the Clinician Administered PTSD Scale (CAPS) as recurrent distressing dreams item and item difficulty falling or staying asleep

- total sleep time (TST).

- Clinical Global Impression of Change (CGIC),

Secondary outcome

- Pittsburgh Sleep Quality Index (PSQI).

- EEG and actimeter indices: (reduction of stage 1 sleep, increase of deep sleep stage)

- Total score on CAPS

- PTSD Diagnostic Scale (PDS)

- Montgomery-Asberg Depression Rating Scale (MADRS)

- Dissociative experiences scale (DES) and Clinician-Administered Dissociative States Scale (CADDS)

- Community Assessment of Psychotic Experiences (CAPE)

Study description

Background summary

Patients with posttraumatic stress disorder (PTSD) and sleeping problems are difficult to treat. The alpha-1 adrenoceptor antagonist Prazosin has been proven effective especially as add-on medication in trauma-related sleep disorders but needs titration to prevent side-effects. Prazosin is currently not easily available in The Netherlands and not always covered by insurance. Doxazosin could be an alternative and may even be better because of longer half-life. Doxazosin has not yet been studied extensively for sleep.

Study objective

To evaluate the effect on sleep and ptsd of the drug Doxazosin Retard in patients with PTSD who also have sleep problems.

Study design

An open label intervention study starting with a run-in placebo period.

Intervention

Doxazosin retard (extended release) 4 mg or 8 mg a day for 6 - 10 weeks.

Study burden and risks

Doxazosin has been used for 25 years for hypertension and benign prostate hypertrophy. It is a relatively safe drug with relatively mild side-effects. In the present study it will be administered for only 6 - 10 weeks. Patients may continue the medication after the study for a maximum of two years.

Patients will wear an actigraph for two weeks and 4 nights of sleep EEG will be done (at home). The actigraph has the size and weight of a watch and can be worn as a watch. The sleep EEG will be done by means of a small ergonomic unit that will be fixated on the trunk and connected with a wire to an plaster on the forehead. This can easily be placed by the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Good speaking and writing in Dutch
- PDS above 18
- CAPS recurrent distressing dreams item score above 5
- CAPS difficulty falling or staying asleep item above 5
- No medication except contraceptives or analgetics like paracetamol
- No alcohol more than two consumptions a day
- Medication use of psychotropics has stopped at least one month before entrance of the study
- If psychotherapy has not been started yet it will not be initiated during the trial; If started it will be paused for the period of the study. Medication with influence on sleep-EEG will not be started during the study period (paracetamol and contraceptives are allowed).

Exclusion criteria

Psychiatric:
- Lifetime schizophrenia,
- schizoaffective disorder,
- bipolar disorder,
- severe depressive disorder (MADRS > 34) (for screening: QIDS > 15)
- cognitive disorder,
- current delirium,

- substance use within 2 months of the study; alcohol is allowed if not more than 2 consumptions a day.
- severe psychiatric instability (including evidence of being actively suicidal or homicidal).
- any behavior which poses an immediate danger to patient or others.;Somatic:
- preexisting hypotension or (anamnestic) orthostatic hypotension
- hypertension unless stable with help of anti-hypertensive medication.
- Known for severe ischaemic heart disease
- disease with strong reduced functioning of the liver.
- Women of childbearing potential with either positive pregnancy test or refusal to use effective birth control method.
- Allergy or previous adverse reaction to doxazosin or other alpha-1 antagonist.
- Hypersensitivity to quinazolinderivates
- Known for hypertrophy of the prostate without treatment.
- Gastro-intestinal obstruction
- oesophageal obstruction
- overflow bladder or anuria with or without progressive renal insufficiency

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	niet van toepassing kan van verschillende firma's
Generic name:	Doxazosinmesilate

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	30-08-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-11-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-09-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28526
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-001548-23-NL
CCMO	NL41043.058.12
OMON	NL-OMON28526