Doxazosine voor PTSS, met name voor de slaapstoornissen.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28526

Source
Nationaal Trial Register

Brief title
DoPS

Health condition

Posttraumatic stress disorder
Sleeping problems

Sponsors and support

Primary sponsor: ParnassiaGroep, PsyQ
Source(s) of monetary or material Support: ParnassiaGroep, PsyQ

Intervention

Outcome measures

Primary outcome

1. 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;

2. Total sleep time (TST);

3. The MIRECC version of the Global Assessment of Functioning scale.

Secondary outcome

1. Pittsburgh Sleep Quality Index (PSQI);

2. Ambulatory sleepregistration (Neuroporti) and actimeter indices;

3. Total score on CAPS;

4. PTSD Diagnostic Scale (PDS);

5. Montgomery-Asberg Depression Rating Scale (MADRS);

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

7. Prodromal Questionnaire (PQ-16).

Study description

Background summary

N/A

Study objective

N/A

Study design

1. Start: All baseline measurements (CAPS, PDS, CADDS, MADRS, PQ-16, MIREC-GAF, DES, PSQI, Possible side-effects, pulse-bloodpressure) except sleepregistration and actimeter;

2. After two weeks: Sleepitems of CAPS, PDS, CADDS, MIREC GAF, pulse-bloodpressure, side-effects;

3. After two weeks start of one week sleepregistration and actimeter, and after three weeks also: CAPS, PDS, CADDS, MADRS, PQ-16, MIREC-GAF, DES, PSQI, Possible side-effects, pulse-bloodpressure;

4. Five weeks: Sleepitems of CAPS, PDS, CADDS, MIREC GAF, pulse-bloodpressure, side-effects;

5. Seven weeks: Sleepitems of CAPS, PDS, CADDS, MIREC GAF, pulse-bloodpressure, side-effects;

6. Nine weeks: Sleepitems of CAPS, PDS, CADDS, MIREC GAF, pulse-bloodpressure, side-effects;

7. After nine weeks: One week of ambulatory sleepregistration and actimeter and CAPS, PDS, CADDS, MADRS, PQ-16, MIREC-GAF, DES, PSQI, Possible side-effects, pulse-bloodpressure.

Intervention

After three weeks of placebo-use and baseline measurements including one week sleepregistration participants use for 2 weeks 4mg doxazosine with extended release then go to 8mg if possible. After two more weeks use of doxazosin extended release measurements are repeated.
During the trial several times some measurements will be taken and pulse and bloodpressure measured.

Contacts

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Eligibility criteria

Inclusion criteria

1. Good speaking and writing in Dutch;

2. PDS above 18;

3. CAPS recurrent distressing dreams item score above 5 - CAPS difficulty falling or staying asleep item above 5;

4. No medication that affects sleep (e.g. contraceptives or analgetics like paracetamol are allowed);

5. No alcohol more than two consumptions a day;

6. Medication use of psychotropics has stopped at least one month before entrance of the study;

7. 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:

1. Lifetime schizophrenia;

2. Schizoaffective disorder;

3. Bipolar disorder;

4. Severe depressive disorder;

5. Cognitive disorder;

6. Current delirium;

7. Substance use within 2 months of the study; alcohol is allowed if not more than 2 consumptions a day;

8. Severe psychiatric instability (including evidence of being actively suicidal or homicidal);

9. Any behavior which poses an immediate danger to patient or others.

Somatic:

1. Preexisting hypotension or (anamnestic) orthostatic hypotension;

2. Hypertension unless stable with help of anti-hypertensive medication;

3. Known for severe ischaemic heart disease;

4. Disease with strong reduced functioning of the liver;

5. Women of childbearing potential with either positive pregnancy test or refusal to use effective birth control method;

6. Allergy or previous adverse reaction to doxazosin or other alpha-1 antagonist;

7. Hypersensitivity to quinazolinderivates;

8. Known for hypertrophy of the prostate without treatment;

9. Gastro-intestinal obstruction;

10. Oesophageal obstruction;

11. Overflow bladder or anuria with or without progressive renal insufficiency.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37075
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3678
NTR-old	NTR3848
CCMO	NL41043.058.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37075

Study results

Summary results
N/A