Doxazosine voor PTSS, met name voor de slaapstoornissen.

Gepubliceerd: 11-02-2013 Laatst bijgewerkt: 15-05-2024

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28526

Bron
NTR

Verkorte titel
DoPS

Aandoening

Posttraumatic stress disorder
Sleeping problems

Ondersteuning

Primaire sponsor: ParnassiaGroep, PsyQ
Overige ondersteuning: ParnassiaGroep, PsyQ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-02-2013
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37075
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A