Amitriptyline en mirtazapine bij langdurige slapeloosheid

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Compared to placebo treatment with low dose amitriptyline or mirtazapine during 16 weeks will improve subjective insomnia in insomnia disorder patients in general practice.

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

Samenvatting

ID

NL-OMON22210

Bron
Nationaal Trial Register

Verkorte titel
DREAMING

Aandoening

insomnia disorder
langdurige slapeloosheid

Ondersteuning

Primaire sponsor: VU Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of the study is the insomnia severity as measured by the Insomnia Severity Index (ISI) (Morin e.a. 2011). The ISI is a 7-item questionnaire scored on a 5-point

Likert scale reflecting the severity of both nighttime and daytime aspects of insomnia disorder as perceived by the participant in the last 2 weeks with scores ranging from 0 (no insomnia) to 28 (severe insomnia). The ISI is the recommended outcome measure in insomnia trials (Buysse e.a. 2006) and is a valid and reliable instrument as an outcome measurement (ref). It possesses adequate internal consistency and is sensitive to changes in perceived sleep difficulties over time (Bastien e.a. 2001; Morin e.a. 2011). The total score can be interpreted as follows: absence of insomnia (0–7); sub-threshold insomnia (8–14); moderate insomnia (15–21); and severe insomnia (22–28) (Morin e.a. 2011). Insomnia will be evaluated at each time point: baseline, 6 weeks, 12 weeks, 20 weeks and 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Although non-pharmacological treatment is first choice, insomnia disorder patients often request at some point concomitant sleep medication. Clinical experience suggests that low dose sedating antidepressants might be effective. General practitioners increasingly prescribe off label amitriptyline and mirtazapine to promote sleep maintenance. However, controlled-data to support this off label prescription practice is lacking. This study aims to investigate the efficacy of treatment with amitriptyline (10-20mg) and mirtazapine (7,5-15mg) during 16 weeks compared to placebo for insomnia disorder in general practice.

Doel van het onderzoek

Compared to placebo treatment with low dose amitriptyline or mirtazapine during 16 weeks will improve subjective insomnia in insomnia disorder patients in general practice.

Onderzoeksopzet

baseline, 6 weeks, 12 weeks, 20 weeks, 52 weeks.

Onderzoeksproduct en/of interventie

The investigational treatment, on top off usual care, consists of one tablet of amitriptyline (10 mg) or mirtazapine (7.5 mg) or an identical appearing placebo per night during 16 weeks. During treatment, participants visit their GP at least twice (at week 3 and week 14) to evaluate their sleep and treatment satisfaction. In addition, at 3 weeks GP and participant can opt to double the dosage (2 units per night). At 14 weeks the GP and participant talk through stopping the trial medication at 16 weeks in case of single dosages and in case of double dosages, lowering from double to single dosage from 14 weeks onwards and stopping treatment at 16 weeks. During treatment and follow-up, care as usual of the participant’s GP continues, without restrictions.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Insomnia Disorder, clinical assessment based on the DSM-5 criteria, i.e. a predominant complaint of dissatisfaction with sleep quantity or quality for three or more days a week during more than three months, resulting in significant daytime impairment despite sufficient opportunity to sleep (DSM-5)2.
2. Non-pharmacological treatment according to the Dutch general practice guideline (including sleep hygiene advice and cognitive behavioural approaches) is deemed insufficient by patient and GP.
3. Consultation of the GP for a sleep medication request, other than for occasional incidental nights or specific period (e.g. traveling).
4. Aged between 18 and 85 years.*
5. Enlisted as patient in one of the participating general practices during the treatment and safety monitoring period.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

6. Insomnia secondary to another medical condition, e.g. OSAS, comorbid major depression,

chronic pain.
7. Amitriptyline or mirtazapine is contra-indicated or would pose additional risks based on information known to the GP in usual care, i.e.: allergy for amitriptyline or mirtazapine; cardiac arrhythmia/cardiac blockade/long QT syndrome/Brugada syndrome/family history of acute cardiac death/recent myocardial infarction (within the past 90 days)/angina pectoris/coronary insufficiency; severe renal insufficiency (GFR < 10); severe liver dysfunction; epilepsy; ocular hypertension/glaucoma; bipolar affective disorder; concurrent alcohol or drug abuse/addiction; suicide risk; vulnerability due to known unstable health situation, according to GP.
8. Pregnancy, lactation or wish to become pregnant in the next 6 months
9. Terminal illness
10. Potential drug-drug interactions: chronic use of psychotropic drugs (including anxiolytics***, antidepressants, antipsychotics, and anticonvulsants and stimulants); concurrent use of oral antimycotics; enzyme inductors, antiretroviral drugs, cimetidine and clonidine.
11. Prescription of amitriptyline or mirtazapine for insomnia in the past year.
12. Being unable to follow study instructions and fill out the study questionnaires (in Dutch).
13. Isolated sleep initiation problem (i.e. without problems maintaining sleep or early-morning awakening problems).****
14. Doing night shifts on a regular basis.
15. Wish to continue (over-the-counter) sleep aids containing melatonin, St John’s worth, cannabis or antihistamines.
16. Concurrent participation in clinical intervention study interfering with the DREAMING intervention and study procedures.

*** Incidental use of BZRAs for sleep in the preceding months is allowed.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland
Status: Werving nog niet gestart

(Verwachte) startdatum:	02-01-2019
Aantal proefpersonen:	156
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data collection is planned to take place until summer 2022 and anonymized data will be archived after 15 years. Study protocol and statistical analysis plans will be available. Data sharing of aggregated or anonymized participant data for scientific purposes within the informed consent of the study participants, is part of the obligatory data management protocol of the funding agency. Any requests can be sent to the corresponding author.

Ethische beoordeling

Positief advies

Datum:	27-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5051
NTR-old	NTR7449
Ander register	NL63470.029.17 : 2017-003766-27

Resultaten