Comparison of melatonin, temazepam and placebo for the treatment of sleep problems in hospitalized older patients.

Gepubliceerd: 18-12-2017 Laatst bijgewerkt: 13-12-2022

Acutely hospitalized older patients frequently suffer from inadequate sleep. Insufficient sleep can lead to patient distress and delayed recovery from acute illness or a surgical procedure. Currently, no evidence-based treatments exist for sleeping...

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

Samenvatting

ID

NL-OMON21870

Bron
Nationaal Trial Register

Verkorte titel
MATCH

Aandoening

Sleeping disorder, acute insomnia.
Slaapstoornis, acute insomnia

Ondersteuning

Primaire sponsor: Prof.dr. S.E.J.A. de Rooij
Email: sejaderooij@gmail.com
Telefoon: (050) 3613921
Adress
Hanzeplein 1
9713 GZ Groningen
Kamer Z3.16,
intern postadres: AA-43
Netherlands

Overige ondersteuning: Amsterdams Universiteitsfonds.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sleep quality, measured with the quality of sleep (QOS) parameter of the Leeds Sleep Evaluation Questionnaire (LSEQ).

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of the MATCH study is to investigate the effects of melatonin, temazepam and placebo on sleep quality among acutely hospitalized older patients with sleeping problems.

This study is a multicenter, randomized controlled trial in the Netherlands. A total of 663 patients will be randomized in a 1:1:1 fashion to receive melatonin (n=221), temazepam (n=221) or placebo (n=221). The study population consists of acutely hospitalized patients aged 65 years and older, with new or aggravated sleeping problems for which an intervention is needed. Measurements will be collected at enrolment , daily during hospitalization (with a maximum of 10 treatment days) and at discharge. The primary outcome is sleep quality measured with the Leeds Sleep Evaluation Questionanaire (LSEQ).

Doel van het onderzoek

Acutely hospitalized older patients frequently suffer from inadequate sleep. Insufficient sleep can lead to patient distress and delayed recovery from acute illness or a surgical procedure. Currently, no evidence-based treatments exist for sleeping problems in acutely hospitalized older patients. Benzodiazepines, such as temazepam, are regularly prescribed by physicians, although they have serious side effects; for older patients in particular. Melatonin is proposed as a safe alternative for sleeping problems in acutely hospitalized older patients, but the efficacy of melatonin is unclear in this population. Therefore, the aim of this study is to investigate the effects of melatonin, temazepam and placebo on sleep quality among acutely hospitalized older patients with sleeping problems.

Onderzoeksopzet

Data will be collected at enrolment, daily during hospitalization (with a maximum of 10 treatment days) and at discharge.

Onderzoeksproduct en/of interventie

Patients are randomized to receive 1 out of 3 possible treatments:

Treatment 1: Melatonin

Dose: 1mg daily, ante nocte (with a maximum of 10 days)

Administration: Orally

Treatment 2: Temazepam

Dose: 10mg daily, ante nocte (with a maximum of 10 days)

Administration: Orally

Treatment 3: Placebo (control)

Dose: placebo, ante nocte (with a maximum of 10 days)

Administration: Orally

Contactpersonen

Publiek

intern postadres: AA-43, Kamer Z3.16

Sjanne Bosman
Hanzeplein 1

Groningen 9713 GZ
The Netherlands
050- 36113464

Wetenschappelijk

intern postadres: AA-43, Kamer Z3.16

Sjanne Bosman
Hanzeplein 1

Groningen 9713 GZ
The Netherlands
050- 36113464

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 60 years or older

2. Admitted to the hospital for a medical or surgical reason

3. Experiencing new onset or aggravated sleep
problems, for which an intervention is needed

4. Able to fill out a sleep questionnaire

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inability to speak, understand or write Dutch

2. Lack of decision making capacity

3. Previously diagnosed dementia

4. Transferred from another hospital to one of the study centers, with insufficient information on previous use of sleep medication.

5. Expected stay in hospital of <48 hours

6. Concurrent regular benzodiazepine or melatonin use

7. Alcohol consumption >13 units/week for women and >20 units/week for men

8. Drug interactions with melatonin or contra indications for benzodiazepine use

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	663
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-12-2017
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	NL6730
NTR-old	NTR6908
Ander register	NL55330.018.15 : ABR

Resultaten