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

No registrations found.

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

Summary

ID

NL-OMON21870

Source
Nationaal Trial Register

Brief title
MATCH

Health condition

Sleeping disorder, acute insomnia.
Slaapstoornis, acute insomnia

Sponsors and support

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Source(s) of monetary or material Support: Amsterdams Universiteitsfonds.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1) The other subscales of the LSEQ: getting to sleep (GTS), awakening from sleep (AFS) and behavior following wakening (BFW).

2) Good nights of sleep measured with a Numeric Rating Scale (NRS)
.
3) Objective sleep parameters measured with actigraphy: sleep onset latency in minutes, sleep efficiency, number and duration of wake bouts and time awake after sleep onset in minutes.

4) Side effects related to study medication: Incidence of delirium during hospitalization, cognition, number of falls during hospitalization, complications and length of hospital stay in days.

Study description

Background summary

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).

Study objective

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.

Study design

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

Intervention

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

Contacts

Public

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2018
Enrollment:	663
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6730
NTR-old	NTR6908
Other	NL55330.018.15 : ABR

Study results