Melatonin Against Temazepam in Comparing adverse events in vulnerable elderly Hospitalized patients with sleeping problems

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Primary objective: To investigate whether either melatonin or temazepam is superior to placebo in improving subjective sleep quality and to investigate whether melatonin is non-inferior to temazepam in acute hospitalized older patients.Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON46069

Source
ToetsingOnline

Brief title
MATCH

Condition

- Sleep disorders and disturbances

Synonym
acute insomnia, Sleeping disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Legaat

Intervention

Keyword: Melatonin, Sleep problems, Temazepam, Vulnerable elderly

Outcome measures

Primary outcome

Improvement in sleep quality, as measured the Leeds Sleep Evaluation Questionaire (LSEQ)

Secondary outcome

1. Improvement in other subjective sleep parameters: getting to sleep (GTS), awakening from sleep AFS) and behaviour following wakening (BFW), measured by the LSEQ

2. Improvement in objective sleep parameters: reduction in sleep onset latency in minutes, sleep efficiency, number and duration of wake bouts, time awake after sleep onset in minutes, measured by actigraphy

3. Short term cognitive measures (reaction time: digit-symbol substitution test, recall: word-list free-recall procedure)

4. Adverse drug events related to study medication, assessed with the method of Narango.(38)

5. Incidence of delirium during hospitalization

6. Number of falls during hospitalization

7. All complications officially added to the hospitals* complication register

8. Length of hospital stay in days

9. Quality of life, measured by EQ5D

10. Chronic use of sleep medications after discharge

11. Mortality during hospitalization and at follow up

12. Exploratory endpoint: laboratory results on kidney and liver measures, if

available

Study description

Background summary

Sleep problems are common among acutely hospitalized older patients. They can lead to patient distress and delayed recovery
from acute illness or surgical procedure. Often, a pharmacological treatment approach is chosen, mostly with the benzodiazepine
temazepam. This treatment is not evidence based for this indication and specific population. Older patients, who often have
multimorbidity and polypharmacy, are at increased risk of experiencing adverse drug events. Benzodiazepines are among the
drugs most frequently associated with inhospital complications such as falls, fractures, daytime hangover, delirium and respiratory
depression. Melatonin is an endogenous hypnotic and might be a safer alternative for the treatment of sleep problems experienced
by acutely hospitalized older patients.

Study objective

Primary objective: To investigate whether either melatonin or temazepam is superior to placebo in improving subjective sleep quality and to investigate whether melatonin is non-inferior to temazepam in acute hospitalized older patients.
Secondary objectives:
To investigate whether melatonin or temazepam is superior to placebo and to investigate whether melatonin is non-inferior to temazepam in:
- improving additional subjective sleepparameters: getting to sleep (GTS), awakening from sleep (AFS) and behaviour following, wakening (BFW)
- improving objective sleepparameters (sleep onset latency, number of wake bouts, time awake after sleep onset, sleepiness during the day)
- shortterm cognitive measures (reaction time, recall)
- (reduction of) adverse drugreactions related to study medication
- (reduction of) hospital complications (delirium, aspiration, falls, length of hospital stay, readmissions)
- (reduction of) mortality (during hospitalisation, at follow-up)

Study design

Multicentered, 3armed placebo controlled, randomized superiority trial.

Intervention

Patients will be randomized to receive either 1mg melatonin, 10mg temazepam or placebo ante noctem daily for a maximum of ten hospital days

Study burden and risks

Patients will receive either temazepam, melatonin or placebo. Melatonin in a dosage of 1 milligram is not known to show any sideeffects and is considered safe for use by older patients. Consequently, the risks associated with this intervention are considered low. Temazepam has potential sideeffects but as this medication is currently often part of the usual treatment of hospitalized elderly with sleep problems, participation in the study will not expose patients to any extra additional risks. Close monitoring of all possible adverse events related to study medication will take place, and in case any adverse events occur, appropriate measures will be taken in consultation with the attending physician. We do not think that patients who are treated with placebo will be exposed to any additional burden when use of benzodiazepines is withheld from them, because evidence for the effectiveness of pharmacological treatment for hospital related sleep problems is absent. All patients will benefit from increased attention to sleep problems.

Contacts

Public
Academisch Medisch Centrum

Meibergreef 9
AZ 1105
NL
Scientific
Academisch Medisch Centrum

Meibergreef 9
AZ 1105
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- aged 65 years or older
- acutely admitted for a medical or surgical reason
- experiencing new onset or aggravated sleep problems, for which the patient/nurse/treating physician expresses a need for intervention
- willing and medically able to receive therapy according to the protocol for the duration of the study
- able to fill out the sleep questionnaire that serves as primary outcome measurement (Leeds Sleep
Evaluation Questionnaire)
- agreeing to informed consent

Exclusion criteria

- no understanding of Dutch or English
- lack of decision making capacity
- previously diagnosed with dementia
- transferred from another hospital to one of the study centres
- transferred from another ward (ICU, CCU etc) to one of the study wards
- expected stay in hospital of <48 hours
- concurrent regular benzodiazepine use (>1 doses/week)
- concurrent regular melatonin use (>1 doses/week)
- alcohol consumption >13 units/week for women and >20 units/week for men(24)
- concurrent use of: chinolones, rifampicine, fluvoxamine, carbamazepine
- having a medical condition that is a contra indication for benzodiazepine use (allergy to benzodiazepines, hepatic failure (Child-Pugh C), kidney disease requiring dialysis, risk of respiratory depression (as clinically esteemed so by the attending physician)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2018
Enrollment:	717
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Melatonin
Generic name:	N-Acetyl-5-methoxytryptamine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Normison
Generic name:	Temazepam
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	08-06-2017
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2015-003368-35-NL
CCMO	NL55330.018.15