Acetaminophen for SLeep Problems in Elderly Patients

Published: 03-03-2011
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Objective: To investigate whether acetaminophen is effective in treating self-reported sleep problems.

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

Summary

ID

NL-OMON36455

Source
ToetsingOnline

Brief title
ASLEEP

Condition

- Sleep disorders and disturbances

Synonym
Insomnia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Elderly patients, Geriatric population, Insomnia, Sleep problems

Outcome measures

Primary outcome

Primary endpoint will be the self-reported sleep problems at the end of

follow-up, measured by means of the Insomnia Severity Index (ISI).

Secondary outcome

Sleep efficiency, sleep onset latency, wake after sleep onset, early morning

awakening, time in bed, total sleep time, registered in a sleep diary

Mark for their nights rest

Adverse effects

Study description

Background summary

The prevalence of sleep disorders increases with age. Sleep disorders have serious health implications and may be relaterd to serious underlying diseases. Many older people use hypnotics like benzodiazepines, although these medications have side effects and often lead to habituation.
If, however, there would be an easy treatment for sleep problems, many patients could benefit. Some people use acetaminophen as a sleeping-pill and are convinced this works. Few is known about the effect of acetaminophen at sleep. Acetaminophen might be a simple and cheap treatment for sleep disorders with low side effects. The ASLEEP study could contribute to our knowledge about treatment of sleep problems.

Study objective

Objective: To investigate whether acetaminophen is effective in treating self-reported sleep problems.

Study design

A randomized, multicenter placebo controlled double-blind trial.

Intervention

Acetaminophen 1000 mg once daily versus placebo

Study burden and risks

In total, the study takes three weeks plus the visit to the outpatient clinic after 4 to 6 weeks. Patients need not to stay in the hospital. Neither do they have to change their regular medication. During the study, they should fill in the sleep diary every day and the ISI weekly. At the end of follow-up, they will return to the outpatient clinic of their hospital or there will be contact by phone. This final control will be done, when possible, at the same time of their regular check-up.
The risks associated with this study consist of the possible adverse effects of acetaminophen. This is widely used an analgesic and has proved to be effective and safe. Even though, close monitoring of study participants will take place for assessment of defined side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Aged * 65 years
Subjective sleep problems during > 1 month, at least once a week
Patients must be willing and medically able to receive therapy according to the protocol for the duration of the study
Patients must be able to give informed consent

Exclusion criteria

Patients using acetaminophen chronically because of pain or who have an indication to start with it (VAS score > 6).
Patients, men and women, who have <6 points on the Pittsburgh Sleep Quality Index
MMSE of <18
Patients who will be admitted to the hospital directly after the visit of the outpatient clinic.
Patients who sleep badly because of (treatable) social, psychic or somatic reasons:
Acute heart failure needing diuretic treatment
OSAS
A depression needing the start of antidepressants
A delirium or anxiety disorder
Recent life event, e.g. loss of a loved one
Planned removal to a nursing home
Life expectancy less than three months according to the attending physician
Liver insufficiency: alanine aminotransferase > 120 U/l
Suicidal tendencies according to the attending physician
Alcohol abuse > 4 units/day

Study design

Design

Study phase:	3
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):	01-07-2011
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	acetaminophen
Generic name:	acetaminophen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	03-03-2011
Application type:	First submission
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	EUCTR2010-023517-57-NL
CCMO	NL33732.018.10