Acetaminophen for sleep problems in the elderly.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21250

Source
Nationaal Trial Register

Brief title
ASLEEP

Health condition

Sleep problems, in particular insomnia.

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Academic Medical Center

Intervention

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

In a subgroup of 15 patients we will measure the periods of wake and sleep with an actigraph during the three weeks of the study.

Study description

Background summary

The prevalence of sleep disorders increases with age. Sleep disorders have serious health implications and may be related 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.

Therefore, we want to conduct a double-blind, randomized, placebo-controlled trial to investigate if acetaminophen is effective in treating self-reported sleep problems in a geriatric population.

Study objective

Acetaminophen is effective in treating self-reported sleep problems, in particular insomnia.

Study design

Inclusion during one year.

Measurements at baseline and after 1 and 3 weeks. Patients will fill in a sleepdiary during 3 weeks.

Intervention

Acetaminophen versus placebo.

Acetaminophen will be given in a dosis of 1000 mg a day during two weeks. No medication will be taken in the first week.

Contacts

Public
Postbus 22660
E.M.M. Glind, van de
AMC, J1B-210-1
Amsterdam 1100 AD
The Netherlands
Scientific
Postbus 22660
E.M.M. Glind, van de
AMC, J1B-210-1
Amsterdam 1100 AD
The Netherlands

Eligibility criteria

Inclusion criteria

1. Aged ¡Ý 65 years;

2. Subjective sleep problems during > 1 month, at least once a week;

3. Patients must be willing and medically able to receive therapy according to the protocol for the duration of the study;

4. Patients must be able to give informed consent.

Exclusion criteria

1. Patients using any acetaminophen on a regular basis (at least once a day) because of pain or who have an indication to start with it (VAS score > 6);

2. Patients who will be admitted to the hospital directly after the visit of the outpatient clinic;

3. MMSE <18 (26);

4. ¡Ü 5 points on the Pittsburgh Sleep Quality Index (27);

5. Patients who sleep badly because of (treatable) social, psychic or somatic reasons:

A. Acute heart failure needing diuretic treatment;

B. OSAS;

C. A depression needing the start of antidepressants;

D. A delirium or anxiety disorder;

E. Recent life event, e.g. loss of a loved one;

F. Planned removal to a nursing home in the coming three weeks;

G. Life expectancy less than three months according to the attending physician;

H. Other reasons, to be assessed and motivated by the attending physician.

6. Liver insufficiency: Alanine aminotransferase > 120 U/l, determined in the last six months;

7. Daily alcohol intake ¡Ý 4 units a day;

8. Suicidal tendencies to be assesed by the attending physician;

9. Participation in other trials concerning sleep.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	10-02-2011
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	NL2619
NTR-old	NTR2747
Other	METC AMC : 10/267
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A