Acetaminophen for sleep problems in the elderly.

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

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

Samenvatting

ID

NL-OMON21250

Bron
NTR

Verkorte titel
ASLEEP

Aandoening

Sleep problems, in particular insomnia.

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint will be the self-reported sleep problems at the end of follow-up, measured by means of the Insomnia Severity Index (ISI).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Inclusion during one year.

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-02-2011
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	NL2619
NTR-old	NTR2747
Ander register	METC AMC : 10/267
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A