

# Acetaminophen for Sleep Problems in Elderly Patients

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Sleep disorders and disturbances
<b>Study type</b>	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 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.

### 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

### Public

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### Scientific

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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  $\geq$  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