Assessment of next-morning driving performance after middle of the night administration of zolpidem tartrate sublingual tablet 3.5 mg in healthy adult volunteers: single-center, double-blind, randomized, placebo-controlled, four-way crossover study

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The aim of the study is to assess the risk of impaired driving in the morning at 3 and 4 hours after a middle-of-the-night dose of zolpidem tartrate sublingual tablet 3.5 mg.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34606

Source
ToetsingOnline

Brief title
Zolpidem sublingual and driving performance

Condition

- Other condition
- Sleep disturbances (incl subtypes)

Synonym
insomnia; sleeplessness

Health condition

onderzoek betreft gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Transcept Farmaceuticals, Inc
Source(s) of monetary or material Support: Transcept Pharmaceuticals;Inc.

Intervention

Keyword: driving performance, placebo-controlled, zolpidem, zopiclone

Outcome measures

Primary outcome

Impaired Drivers, where Impaired Driver is a binary indicator defined for

subject i to be 1 if TreatmentSDLP[i] - PlaceboSDLP[i] > 2.5 cm and zero

otherwise.

The abbreviation SDLP is Standard Deviation of Lateral Position (in cm). This

is an index of weaving of the car on the road.

Secondary outcome

- Impaired Drivers, where Impaired Driver is a binary indicator defined for

subject i to be 1 if:

a.TreatmentSDLP[i] - PlaceboSDLP[i] > 3.5 cm and zero otherwise,

b. TreatmentSDLP[i] - PlaceboSDLP[i] > 2 cm and zer otherwise.

- SDLP in centimeters

- Standard Deviation of Speed (SDS) in km/h

Study description

Background summary

Ideally, a hypnotic administered in the middle-of-the-night by individual having sleep maintenance problems would allow them to return to sleep rapidly and wake up with minimal residual sedating effects. As shown in previous studies, zolpidem tartrate sublingual tablet 3.5 mg appears to be a possible candidate for middle-of-the-night administration. It is, however, not known whether this hypnotic still produces residual sedating effects 3 and 4 hours following administration. Possible residual effects may affect reaction time and, consequently, impair activities such as driving performance.

Study objective

The aim of the study is to assess the risk of impaired driving in the morning at 3 and 4 hours after a middle-of-the-night dose of zolpidem tartrate sublingual tablet 3.5 mg.

Study design

The study is conducted according to a double-blind, randomized, placebo-controlled, four-way crossover design.

Intervention

-Single evening administration of zopiclone 7.5 mg, followed by single middle-of-the-night administration of placebo
-Single evening administration of placebo, followed by single middle-of-the-night administration (04:15 or 05:15 hours) of zolpidem tartrate sublingual tablet 3.5 mg
-Single evening administration of placebo, followed by single middle-of-the-night adminstration of placebo

Study burden and risks

Subjects will visit the study centre for four test periods, each consisting of an evening, a night and following morning (in total 12 hours, including 8 hours of sleep for each period). During these test periods, subjects are administered a hypnotic or placebo at bedtime and in the middle-of-the-night. The following morning the residual effects on driving performance are investigated by means of a highway driving test.
Before and during test periods, use of medication, alcohol, caffeine, and nicotine is restricted: From one week prior to medical examination en test periods use of medication that may affact driving performance is not allowed;

from 24 hours prior to a test period no alcohol; from 16:00 hours, untill the end of the test the next morning no caffeine containing beverages (e.g. coffee, cola, tea) or food (e.g. chocolate); no smoking during a test period.
Prior to the test periods subjects will be medically examined. This will take approximately 1 hour and a total of 12 mL blood will be drawn for clinical blood analysis. In addition, the driving test will be trained during 1 hour and subjects sleep one night for habituation to the environment and practice of the procedures. This habituation procedure lasts approximately 10 hours. Following the final test period again 12 mL blood will be drawn for clinical blood analysis.
There will be no noticeable risk for participation to this study. Side effects such as daytime sleepiness, loss of muscle tone, dizziness, tiredness and blurred vision may occur. Possible minor side-effects are intestinal problems, increased appetite, decreased libido, and menstrual pains. Alle side-effect are known to be mild and transient. Zopiclone 7.5 mg is known to impair driving performance untill 11 hours after administration.

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

Healthy
Age 21 till 64
Possession of valid driving licence
Sufficient driving experience (at least 3000 km/year over the past three years)

Exclusion criteria

Use of medication that may influence driving performance
Excessive use of alcohol, nicotine or cafeine
Use of drugs
For women: pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2010
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Imovane
Generic name:	zopiclone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Intermezzo
Generic name:	zolpidem
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-04-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-06-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2010-019959-22-NL
ClinicalTrials.gov	NCT01106859
CCMO	NL32176.068.10