

Effects of insomnia and chronic use of hypnotics on driving performance

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON31127

Source

ToetsingOnline

Brief title

Insomnia, hypnotics and driving

Condition

- Sleep disturbances (incl subtypes)

Synonym

sleep problems; insomnia

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: driving performance, hypnotics, insomnia

Outcome measures

Primary outcome

The main study parameter is Standard Deviation of Lateral Position (SDLP in cm) in the highway driving test.

Secondary outcome

Time to speed adaptation (in msec) and brake reaction time (in msec) in the car following test.

Cognitive and psychomotor tests: 15-Word Learning Test; Critical Tracking Task;

Divided Attention Task; Stop Signal Task; Psychomotor Vigilance Task; Digit

Span Backward and Forward.

Subjective evaluations: Subjective alertness Bond & Lader Visual Analogue

Scales.

Study description

Background summary

One of the main problems associated with the use of hypnotics is residual daytime sleepiness the morning after bedtime administration. This poses a crucial problem for users of hypnotics whose activity the next morning involves skilled work and in whom impairment of performance, such as driving a car, could be a danger to themselves or others. It is, therefore, for the safety of patients using hypnotics important to have knowledge on the extent of influence the hypnotics have on their daily activities, particularly driving. Information on the severity of residual effects of hypnotics is mainly derived from experimental studies in young healthy volunteers after administration of a single dose. However, the majority of hypnotic users are elderly (i.e. 55 years or older) and use hypnotics for longer periods, which may result in tolerance towards the residual effects. Moreover, hypnotic users have sleep complaints

which may have deleterious consequences on daytime performance. A hypnotic-induced night of sleep is then expected to improve daytime functioning, despite the possible sedating residual effects of the hypnotic.

Study objective

Aim of the study is to investigate what the influence is of insomnia on driving performance and to what extent this influence is attenuated by the use of hypnotics.

Therefore, over-the-road driving performance of treated and untreated patients complaining of insomnia is compared with that of healthy controls matched for age, gender and annual mileage.

Study design

The study will be conducted according to a 3x2 parallel group design with three groups (users, non-users and matched controls) and two within subject conditions (habituation and baseline).

Study burden and risks

Subjects will visit the study centre and be monitored by one of the investigators for examination during medical screening (2 hours); for training of cognitive tests and highway driving test (4 hours); and for one habituation period and one baseline period consisting of an evening, night and following morning (in total 32 hours, including 16 hours of sleep). Blood samples are drawn during screening (12 mL) and test periods (8 mL). During test periods subjects perform cognitive tests and a highway driving test. An on-the-road driving test has been chosen as it is considered more sensitive than the use of driving simulators. The latter has been shown not to be sensitive enough to predict residual drug effects in the on-the-road driving tests of two classical benzodiazepines.

It is still unclear whether chronic insomnia has significant impairing consequences on daily life routines such as driving a car. Moreover, it is unclear whether use of hypnotics can attenuate the presumed effects of insomnia. In addition it is unknown whether the residual effects hypnotics are absent in chronic users.

This study is relevant in order to inform patients and physicians adequately on the effects of insomnia and the possible residual effects of hypnotics, in particular with respect to their effects on driving performance.

Epidemiological data show some evidence, but the results have not yet been replicated in experimental studies. Therefore, an on-the-road driving test has been chosen as it is considered more sensitive than the use of driving simulators. The latter has been shown not to be sensitive enough to predict residual drug effects in the on-the-road driving tests of two classical benzodiazepines. In addition, the current lack of experimental evidence seems

to be a possible result of a lack of ecologically valid tests.

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 (except for patients with complaints of insomnia)

age 55 year or older

possession of a valid drivers license

average annual driving experience of 3000 km per year over the last three years

Exclusion criteria

abuse of alcohol, nicotine and caffeine

use of medication that might affect driving performance (except hypnotics)

For patients: Sleep-Related Breathing Disorders; Circadian Rhythm Sleep Disorders; Sleep-Related Movement Disorders

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2007
Enrollment:	75
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Imovane
Generic name:	zopiclone
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Mogadon
Generic name:	nitrazepam
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Normison
Generic name:	temazepam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Stilnoct
Generic name:	zolpidem
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Temesta
Generic name:	Lorazepam
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
Date:	08-05-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	27-06-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	04-06-2008
Application type:	Amendment
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	EUCTR2007-002154-28-NL
CCMO	NL17428.068.07