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Insomnia, hypnotics and driving

Submission date	Recruitment status	[_] Prospectively registered
21/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/09/2019	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EPU-P31

Study information

Scientific Title

Effects of insomnia and chronic use of hypnotics on driving performance: a parallel group comparison trial

Study objectives
The present study aims to determine whether driving performance of chronic users of hypnotics and unmedicated insomnia patients differs from normal sleepers of the same age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Maastricht University and University Hospital of Maastricht approved on the 20th June 2007 (ref: MEC 07-3-040)

Study design
3 x 2 parallel group comparison trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Insomnia

Interventions
3 x 2 parallel group design with three groups (chronic users, unmedicated insomnia patients, controls) and two within subject conditions (habituation and baseline).

Subjects were individually trained to perform the laboratory tests during two sessions of approximately 1.5 hours within 10 days before their first night. After training the subjects underwent two nights of sleep evaluation. The first night was a habituation and practice condition to familiarize subjects with the sleeping facilities and polysomnographic and test procedures. The second night was considered as the actual test condition.

A test condition started in the evening of Day 1, when the subjects arrived at the site at approximately 19:00 hours, and lasted until Day 2, when they were discharged at approximately 11:45 hours. On arrival at the sleeping facility, subjects rated their subjective feelings and subjective sleepiness. From 19:30 hours until 20:30 hours they performed the first session of laboratory tests, comprising the Word Learning Test immediate and first delayed recall, the

Critical Tracking Task, the Divided Attention Task, the Psychomotor Vigilance Task, the Stop Signal Task, and the Digit Span forward and backward. Hereafter, electrodes for polysomnographic recording were attached.

Subjects retired to bed at 23:30 hours. Immediately preceding retiring, subjects in the chronic users group ingested their own prescribed hypnotic, whereas subjects in the unmedicated insomniacs group and controls did not ingest medication. Subjects were awakened at 07:30 hours and after arising a light standardized breakfast was served. At 08:00 hours subjects evaluated sleep quality and duration, and feelings of daytime sleepiness and alertness. Subsequently, they started the second session of laboratory tests, comprising the Word Learning Test second delayed recall and recognition, the Critical Tracking Task, the Divided Attention Task, the Psychomotor Vigilance Task, and the Digit Span forward and backward. At 9:00 hours blood samples were taken from the chronic users to determine serum concentrations of hypnotics before driving. Thereafter subjects were transported to the Highway Driving Test which they performed between 09:30 and 10:30 hours. Upon completion subjects rated the mental effort it took to perform this driving test, and subsequently they conducted the Car-Following Test. Upon completion of this test subjects returned to the testing facilities for removal of the electrodes and were discharged.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Standard Deviation of Lateral Position (SDLP in cm) in the highway driving test

Secondary outcome measures
1. Time to speed adaptation (in sec) and brake reaction time (in msec) in the car following test
2. Cognitive and psychomotor tests

Overall study start date
01/06/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Healthy (except for patients complaints of insomnia)
2. Aged 55 year of older, either sex
3. Possession of a valid drivers license
4. Average annual driving experience of 3000 km per year over the last three years

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
75 patients (25 in each group)

Total final enrolment
63

Key exclusion criteria
1. Abuse of alcohol, nicotine and caffeine
2. Use of medication that might affect driving performance (except hypnotics)
3. For patients:
3.1. Sleep-related breathing disorders
3.2. Circadian rhythm sleep disorders
3.3. Sleep related movement disorders

Date of first enrolment
01/06/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Universiteitssingel 40
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Sponsor information

Organisation
Federal Highway Research Institute (Bundesanstalt für Straßenwesen) (Germany)

Sponsor details
DRUID-Project
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Sponsor type
Research organisation

Website
http://www.bast.de

ROR
https://ror.org/046nzaj59

Funder(s)

Funder type
Government

Funder Name
European Union (EU) (Belgium) - Sixth Framework Programme (FP6): Driving Under the Influence of Drug, Alcohol and Medicine (DRUID)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014	19/09/2019	Yes	No