

# Insomnia, hypnotics and driving

<b>Submission date</b> 21/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/09/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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

Maastricht

Netherlands

6229ER

## Sponsor information

**Organisation**

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

**Sponsor details**

DRUID-Project

Brüderstrasse 53

Bergisch Gladbach

Germany  
D-51427  
-  
druid@bast.de

**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?
<a href="#">Results article</a>	results	01/07/2014	19/09/2019	Yes	No