Insomniacs driving after use of sleeping medication

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25980

Source
Nationaal Trial Register

Brief title
EPU-P35

Health condition

insomnia (insomnie)
use of hypnotics (slaapmiddelengebruik)

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: EU

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Highway driving test:

Standard Deviation of Speed (SDSP in km/h)

- Car following test:

Time to Speed Adaptation (TSA, in ms), brake reaction time (BRT, in ms) and Standard Deviation of Headway (SDH).

Cognitive and psychomotor tests:

• 15-Word Learning Test (Immediate and Delayed Recall Scores, Speed and accuracy of Recognition);

• Critical Tracking Task (Average lambda [in rad/s]);

• Divided Attention Task (Tracking Error [in mm], Target Detection Time [in ms];

• Stop Signal Task (Go Reaction Time [in ms], Stop Signal Reaction Time [in ms]);

• Psychomotor Vigilance Task (mean Reaction Time [in ms]; percentage of Lapses [in %];

• Digit Span Backward and Forward (Maximum Forward and Backward Score).

• Subjective evaluations: Subjective alertness assessed by Visual Analogue Scales

Study description

Background summary

Rationale: To date, most experimental studies investigating the next-day residual effects of hypnotics on actual driving performance have been conducted in healthy young volunteers after evening administration of a single dose. This group of subjects differs, however, on two important aspects with the target population, i.e. insomniacs. First, insomniacs have sleeping problems and may therefore benefit from the therapeutic effects of hypnotics. The disturbed sleep in insomniacs may cause significant impairment in daytime performance. Daytime performance after a hypnotic-induced night would be improved compared to performance after a medication-free night. Secondly, a large number of patients are using hypnotics for prolonged periods, which may result in tolerance towards the residual effects. No study has directly compared the residual effects of hypnotics on driving performance between medication-naïve healthy volunteers and insomniacs using hypnotics for prolonged periods.

Objective: The primary objective of the study is to determine whether the residual effects of

zopiclone 7.5 mg on highway driving performance differ between patients complaining of insomnia and frequently using hypnotics, insomnia patients not frequently using hypnotics, and healthy controls, using a one-hour standardized highway driving test in normal traffic.

Study design: A 2x3, double-blind, crossover design comparing the residual effects of zopiclone 7.5 mg and placebo on actual driving performance and cognitive and psychomotor performance in three groups.

Study population: Participants will be a total of 48 participants in this study, divided in three groups:

- 16 individuals complaining of insomnia and frequently using hypnotics (‘users’), defined as an average use of hypnotics of at least four nights per week for more than 3 months

- 16 individuals complaining of insomnia and not using hypnotics (‘non-users’), defined as an average use of hypnotics of less or equal to two nights per week for more than 3 months

- 16 self-defined good sleepers (matched for age, sex, education and driving experience (‘controls’)

Intervention: Subjects receive a single oral dose of zopiclone 7.5 mg or placebo. Balancing of treatments will be accomplished by randomly assigning subjects to one of two treatment sequences (placebo – zopiclone or vice versa).

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

Study objective

Driving performance after administration of zopiclone 7.5 mg is not different between patients complaining of insomnia and frequently using hypnotics, insomnia patients not frequently using hypnotics and matched healthy controls.

Study design

Activity Day 1 Actual Time(h:m)

Arrival and check-in: 20:00

Adverse events

Concomitant medication: 20:00 – 20:30

Attachment Polysomnography electrodes: 20:30

Reminder to make ready for bed: 23:00

Instruction to sleep (drug intake ‘users’): 23:30

Activity Day 2

Wake up subject: 07:30

Standard breakfast

- Sleep Quality Scale [2 min] 08:00–9:00

- Bond and Lader VAS [3 min]

- Cognitive Performance Tests [57 min]

- Word Learning Test Immediate Recall [8 min]

- Critical Tracking Task [3 min]

- Divided Attention Task [12 min]

- Psychomotor Vigilance Task [11 min]

- Stop Signal Task [16 min]

- Digit Span Forward & Backward [5 min]

- Word Learning Test Delayed Recall and Recognition Task [5 min]

Serum concentration: 09:00

Highway Driving Test: 09:30 – 10:45
Car Following Test:

Subjective Driving Quality: 10:45 – 11:10

Intervention

Subjects receive a single oral dose of zopiclone 7.5 mg or placebo. Balancing of treatments will be accomplished by randomly assigning subjects to one of two treatment sequences (placebo – zopiclone or vice versa).

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female

2. Aged 55 years or older

3. Possession of a valid driving license for 3 years or more (for >70 years: Possession of “Declaration of Appropriateness’ (in Dutch: Verklaring van Geschiktheid))

4. Average driving experience of at least 3000 km per year over the last three years

5. Mentally and physically fit to drive

6. Signed Informed Consent Form

7. Good health, in the opinion of the medical supervisor, on the basis of a pre-study physical examination, medical history, vital signs, electrocardiogram, and the results of blood biochemistry, haematology, and serology tests, and urinalysis

8. For patients: complaints of insomnia

Exclusion criteria

1. History of drug or alcohol abuse

2. Presence of significant medical (e.g. cancer), neurological (e.g. dementia, epilepsy, Parkinson), or psychiatric disorders (e.g. psychosis, major depression)

3. Chronic use of medication that affects driving performance (such as anti-epileptics, anti-psychotics, anti-depressants, anti-parkinsonian medication), except hypnotics

4. Drinking more than 6 cups of coffee per day

5. Drinking more than 21 glasses of alcohol per week

6. Smoking more than 10 cigarettes per day

7. BMI over 30 kg/m²

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2008
Enrollment:	48

Type: Actual

Ethics review

Positive opinion
Date: 12-06-2008

Application type: First submission

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
NTR-new	NL1295
NTR-old	NTR1342
Other	: EPU-P35
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A