Insomniacs driving after use of sleeping medication

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25980

Bron
NTR

Verkorte titel
EPU-P35

Aandoening

insomnia (insomnie)
use of hypnotics (slaapmiddelengebruik)

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: EU

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

highway driving test.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

Maastricht University
Fac. of Psychology
Dept. of Neuropsychology & Psychopharmacology
PO Box 616
Tim R.M. Leufkens
Maastricht 6200 MD
The Netherlands
+31 (0)43 3881756

Wetenschappelijk

Maastricht University
Fac. of Psychology
Dept. of Neuropsychology & Psychopharmacology
PO Box 616
Tim R.M. Leufkens
Maastricht 6200 MD
The Netherlands
+31 (0)43 3881756

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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/m^2

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-08-2008
Aantal proefpersonen:	48
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-06-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1295
NTR-old	NTR1342
Ander register	: EPU-P35
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A