The acute effects of oxazepam on actual driving performance and cognitive functions

Published: 24-07-2014
Last updated: 21-04-2024

Primary objective of this study is to assess the acute dose dependent effects of single doses of oxazepam (10 mg and 30 mg) on driving performance and compare it with a single dose of diazepam 10 mg and placebo.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41122

Source
ToetsingOnline

Brief title
Acute effects of oxazepam on driving

Condition

- Other condition

Synonym
not applicable

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive functions, diazepam, driving, oxazepam

Outcome measures

Primary outcome

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

cm) in the highway driving test.

Secondary outcome

Secondary parameters will be accuracy and/or speed in the following tests:

* Psychomotor Vigilance Test (PVT)

* Critical tracking test (CTT)

* Divided Attention Test (DAT)

* Useful Field of View (UFOV)

* Digit Symbol Substition Test (DSST)

* Postural Balance test (PBT)

* Vienna Test System Determination Test (DT)

* Attention Network Test (ANT)

Study description

Background summary

Benzodiazepines, taken as anxiolytics, remain an important pharmacotherapeutic option to relieve anxiety symptoms. They are generally well-tolerated, but side-effects such as sedation and impaired psychomotor performance can occur.

Epidemiological data has found significant increases of accident risk with benzodiazepines, especially within one or two weeks after prescription and with an increase of dose. Therefore, prescribers and users should be informed about the potential acute impairing effects of anxiolytics on functioning, such as driving performance.
In the Netherlands, oxazepam is regarded as the first choice of treatment for initial relieve of anxiety symptoms. Epidemiological data indicates no increase of crash risk with oxazepam. However, the acute effects of single doses of oxazepam on driving performance have not yet been investigated and not much is known about the impairing effects on cognitive functioning. It is unknown whether there is a difference between the acute effects of a single low dose of oxazepam (10 mg) and a single high dose of oxazepam (30 mg) on driving performance and cognitive functioning.
The acute effects of oxazepam 10 mg and 30 mg will be compared with diazepam 10 mg, which has known impairing effects on driving performance and cognitive functioning.

Study objective

Primary objective of this study is to assess the acute dose dependent effects of single doses of oxazepam (10 mg and 30 mg) on driving performance and compare it with a single dose of diazepam 10 mg and placebo.

Study design

a four-way, double-blind, randomized placebo-controlled, cross-over design to compare the acute effects of two single doses of oxazepam (10 mg and 30 mg) with diazepam (10 mg) and placebo on actual driving performance and a range of cognitive tests.

Intervention

Participants will receive one dose of oxazepam 10 mg, oxazepam 30 mg, diazepam 10 mg, or placebo. Balancing of treatments will be accomplished by randomly assigning participants to one of the four treatment sequences.

Study burden and risks

Volunteers* health will be assessed before treatment during a screening visit (1 hour, including an ECG test and assessment of a medical history questionnaire). Eligible subjects will visit the research unit on six more occasions. The first two sessions include familiarization and practice of the performance tests (approximately 3 hours). Subsequently, they will visit four times for intervention and testing (approximately 7 hours for each condition). The treatments are oxazepam 10 mg, oxazepam 30 mg, diazepam 10 mg, and placebo. At the end of testing on intervention days participants will be

transported home by taxi. Total time spent by the participants will be approximately 32 hours.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- healthy males or females, in the opinion of the medical supervisor, based on a pre-study physical examination, medical history, vital signs, electrocardiogram, and the results of blood chemistry, haematology, and urinalysis
- aged between 23 and 50 years (inclusive)
- BMI between 19 and 29 m2/kg (inclusive)
- possession of a valid driving license for 4 years or more
- driving experience of at least 3000 km per year on average
- good sleepers

- subjects should sign an Informed Consent Form

Exclusion criteria

- history of mental illness
- sleep disorders such as insomnia and narcolepsy
- history of or current drug or alcohol abuse
- current use of psycho-active medication, and inability to stay abstinent during the study
- excessive alcohol use, defined as drinking more than 21 glasses of alcohol per week
- excessive caffeine use, defined as drinking 5 or more cups of coffee per day
- smoking more than 10 cigarettes per day

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-12-2014
Enrollment:	27
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Serax
Generic name:	oxazepam
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Valium
Generic name:	diazepam
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-07-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-11-2014
Application type:	First submission
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	EUCTR2014-001801-42-NL
CCMO	NL49512.068.14
Other	nog niet beschikbaar

Study results

Date completed:	13-05-2015
Actual enrolment:	27

Summary results
Trial is onging in other countries