The effects of ceasing opioid, benzodiazepine, or Z-hypnotic drug use on measures of driving performance and postural balance.

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

Summary

ID

NL-OMON44190

Source
ToetsingOnline

Brief title
The effects of ceasing sedative medications on driving and balance.

Condition

- Other condition
- Sleep disturbances (incl subtypes)
- Anxiety disorders and symptoms

Synonym
chronic pain, Insomnia

Health condition

Pijnklachten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Balance, Medication, Sedative, Traffic

Outcome measures

Primary outcome

The main outcome parameter of the study will be the standard deviation of the lateral position (SDLP) of the test vehicle during a standardized on-the-road driving test.

Secondary outcome

Furthermore, a neurocognitive test battery consisting of neuropsychological tests and laboratory computer tasks will be used. Also, a driving simulator test will be included. For our secondary objective, a postural balance task is included which measures body sway.

Study description

Background summary

Benzodiazepines, Z-hypnotics, and opioids are classes of psychoactive medications that have been linked to increased accident risk, i.e. traffic accidents and falling, based on epidemiological findings. Furthermore, experimental data demonstrates the acutely intoxicating effects of these medications on measures of driving performance and postural balance. Continued use of these medications is often advised against due to tolerance development, the risk of becoming dependent, or the development of long-term side effects. Hence, continued use can be an unnecessary risk to the patient. The Jessa

Hospital in Hasselt, Belgium, has launched an initiative to identify patients using these and other drugs inappropriately or unnecessarily, and consequently attempts to withdraw these patients from these drugs. Some evidence supports the effectiveness of withdrawal interventions with respect to falling risk. However, when it comes to driving performance little *if any- evidence exists.

Study objective

The aim of this study is primarily to investigate the effects of a withdrawal intervention on measures of driving performance in a clinical population that uses benzodiazepines, Z-hypnotics, or opioid analgesics chronically. As a secondary objective, this study also aims to replicate previous findings that demonstrate that fall risk decreases after cessation of psychoactive medications by observing the effects of cessation on measures of postural balance.

Study design

The proposed study is a 3 (groups) by 2 (repeated measures) mixed design. Participants who use a medication of interest chronically will be invited to have their medication schedule examined and revised if applicable. Patients who are advised to cease the use of a medication of interest will be invited for a training day, a pre-cessation, and a post-cessation testing moment. Patients are divided into two groups based on the pharmacodynamic properties of their medications. One group will consist of patients using a benzodiazepine or a Z-hypnotic, while the other group will include opioid users. Furthermore, a control group will be included to match the patient sample with respect to age, gender, and driving frequency. Control participants will be excluded if they are currently using any psychoactive medication.

Intervention

Potentially eligible participants are invited to have their medication schedule examined and, if applicable, revised by the collaborating clinicians at the Jessa Hospital in Hasselt. The decision to alter the patients' medication will be made only by the physician at the Jessa hospital and will always aim to meet the patients' best medical interest. Therefore, it might well be that it is decided that nothing will change to the medication regimen of the patient. The general practitioner of the patient will always be informed about any changes to the medication regimen of the patient.

Study burden and risks

The primary source of concern for the participants* well-being is the possibility of withdrawal effects. However, gradually tapering off the medication should prevent or minimize the occurrence of withdrawal effects.

Secondarily, fatigue due to testing can also occur. However, sufficient breaks are included during which drinks and snacks are provided. Finally, simulator testing can induce complaints similar to motion sickness. Participants will be informed of this possibility before test initiation. Participants will also be informed that they can decide to stop simulator testing whenever they feel too uncomfortable to continue. In addition, the test supervisor will stop the testing whenever visible signs of discomfort occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Possession of a valid driver's license for at least 3 years.
A driving frequency of at least once a week.
A weekly driving distance of at least 50km.

Being able to operate a manual transmission
The chronic (at least 90 days per year) use of a relevant medication (for patients only).

Exclusion criteria

Mini Mental State Examination score of less than 24.
Deemed medically unfit to drive based on a medical screening.
Recurrent illicit or recreational drug use.
Excessive alcohol use (>21 beverages per week)
Not willing to consider discontinuation of the use of a medication of interest in case this is advised by a clinician (patients only).
The use of any psychoactive substance (control participants only)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2018
Enrollment:	94
Type:	Actual

Ethics review

Approved WMO

Date:	29-08-2017
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-11-2017
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	EUCTR2017-003365-99-NL
CCMO	NL62809.068.17