A double blind placebo-controlled crossover study to determine the effects of atomoxetine on event-related potentials in response to auditory oddball stimuli during an on-the-road driving test in adult patients with attention-deficit hyperactivity disorder

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON31557

Source
ToetsingOnline

Brief title
Effects of atomoxetine on attention and driving in adult ADHD

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, Attention Deficit Hyperactivity Disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ADHD, Atomoxetine, Driving, ERP

Outcome measures

Primary outcome

Primary outcome measure of the driving test are standard deviation of lateral position (SDLP), mean lateral position, standard deviation of speed (SDS), and mean speed. The outcome measures of the auditory oddball task are reaction speed, missers, false alarms, and reaction time variability. The outcome measures of the EEG measured during presentation of the auditory oddball task and during driving are ERPs (MMN, P3a, P3b, RON) and EEG power (Alpha, beta, theta, delta). The main outcome measures of the stop signal task are the mean reaction time (MRT) and stop signal reaction time (SSRT). The ERPs that will be measured in response to the stop signal task are the P3 and N1.

Secondary outcome

N.A.

Study description

Background summary

Driving a car is an important factor in daily life. For patients that are treated with methylphenidate it is often prohibited to drive a car in the

Netherlands. However, several studies have shown a positive effect of methylphenidate in ADHD patients on driving performance and related tasks. Since april 2005 a new treatment for ADHD is available, namely atomoxetine. The effects of atomoxetine on driving ability have not been investigated yet. Inattention and distraction of the driver is often the cause of traffic accidents. ADHD patients have attention deficits and are easily distracted. To gain more insight into the attentional processes during driving in ADHD patients, and in the possible improvement with atomoxetine, we propose to study attentional processes during driving with and without atomoxetine in adult ADHD patients. This will be investigated by presentation of an auditory oddball paradigm during driving and the measurement of event-related potentials (ERPs) in reaction to these auditory stimuli.
Deficient inhibitory control is a core symptom of ADHD. Inhibitory control and related ERPs improve after methylphenidate intake. Recently an improvement of inhibitory control has also been found after intake of atomoxetine. To replicate this study and to investigate the effects of atomoxetine on the ERPs related to inhibitory control, a stop signal task will be performed and ERPs will be recorded under influence of atomoxetine and placebo.

Study objective

The aim of the study is to investigate the effects of atomoxetine on driving performance compared to placebo in 30 adult patients with ADHD. An auditory oddball paradigm will be presented and EEG will be measured during driving to gain insight in the attentional processes during driving in ADHD patients (with atomoxetine and placebo). Furthermore, the effects of atomoxetine and placebo on inhibitory control and related ERPs will be investigated.

Study design

Patients take part in the study for 2-3 weeks. Each patient will participate 3 days (approxamately 4 hours per day), including one training/screening day. The study is a dubbel blind cross-over randomized study. Participation will include performing an on-the-road driving test, an auditory oddball task, and performing the on-the-road driving test while the auditory oddball task is presented simultaneously. ERPs will be recorded in response to the auditory oddball stimuli. Finally, a stop-signal-task will be performed and ERPs will be recorded in response to the stop-signal-task.

Intervention

Intervention consists out of one dosage atomoxetine and one dosage of placebo on two different test days.

Study burden and risks

The risk for the patients is the risk of participating in normal traffic. Driving with distracting stimuli can be an extra risk. The risk of driving in normal traffic with distracting stimuli will be abolished by the presence of a licensed driving instructor who is provided with a double brake and clutch system and who can end the test if nescessary. Further, the risk for the patient consists of intake of atomoxetine. However, atomoxetine is a registred medicine prescribed for use in ADHD, abolishing the risk to a minimum. The burden for the patients is delay of ADHD medication treatment for two weeks.

Contacts

Public
Universiteit Utrecht

Sorbonnelaan 16
3584 CA Utrecht
NL
Scientific
Universiteit Utrecht

Sorbonnelaan 16
3584 CA Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Adult men and women diagnosed with ADHD
-Written informed consent

-Possession of a valid driver's license for at least 3 years
-For women of childbearing potential, a negative urine beta-HCG pregnancy test result at test days
-Normal static binocular acuity, corrected or uncorrected
-Normal hearing
-Be considered as reliable and mentally capable of adhering to the protocol

Exclusion criteria

-Depression or anxiety disorder, unless controlled and stable with medication
-IQ<75
-Current drug use (positive urine drug screen on the presence of amphetamines, barbiturates, benzodiazepines, cocaine, and opiates at test days)
-Use of psychoactive medication
-Positive alcohol breath test
-Prior enrolment in the same study
-Participation in another clinical trial

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Strattera

Generic name:	Atomoxetine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-07-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-02-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2007-001855-20-NL
CCMO	NL18258.041.08