# The effects of atomoxetine on brain potentials in response to auditory distracting sounds during driving in adults with attention-deficit hyperactivity disorder.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24935

**Source**
Nationaal Trial Register

**Health condition**

ADHD, atomoxetine, electroencephalography (EEG), event-related potential (ERP), attention, inhibition

### Sponsors and support

**Primary sponsor:** Utrecht University
Faculty of Science
Department of Psychopharmacology
**Source(s) of monetary or material Support:** Utrecht University
Faculty of Science
Department of Psychopharmacology

### Intervention

## Outcome measures

### Primary outcome

Primary outcome measures are:

The weaving of the car during the driving test, i.e. the Standard Deviation of Lateral Position (SDLP), the P3a measured in an auditory oddball task which is suggested to reflect attention orienting/distraction, and the stop signal reaction time and P3 measured in a stop task which is suggested to be associated with response inhibition.

### Secondary outcome

Secondary outcome measures are:

Mean speed, meen lateral position, and Standard Deviation of Speed (SDS) for the driving test.

Mismatch negativity (MMN), P3b and reorienting negativity (RON), reaction times, false alarms, and misses for the auditory oddball task.

N1, mean reaction time, reaction time variability, percentage correctly inhibited, percentage errors, and percentage ommisions in the stop task.

# Study description

### Background summary

N/A

### Study objective

N/A

### Study design

Each measure is acquired twice, timepoint: 0 and 5-7 days.

### Intervention

1. Atomoxetine;

2. Placebo.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Adult men and women diagnosed with ADHD (DSM IV, APA 1994), aged 21-55 years;

2. Written informed consent;

3. Possession of a valid driver’s license for at least 3 years;

4. For women of childbearing potential, a negative urine beta-HCG pregnancy test result at test days;

5. Normal static binocular acuity, corrected or uncorrected;

6. Normal hearing;

7. Be considered as reliable and mentally capable of adhering to the protocol.

## Exclusion criteria

1. Depression or anxiety disorder, unless controlled and stable with medication (SSRI);

2. IQ<75;

3. Current drug use (positive urine drug screen on the presence of amphetamines (including MDMA), barbiturates, benzodiazepines, cocaine, and opiates at test days);

4. Use of psychoactive medication, except SSRI;

5. Positive alcohol breath test;

6. Prior enrolment in the same study;

7. Participation in another clinical trial.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-09-2009 |
| Enrollment: | 30 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 11-11-2009 |
| 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 | NL1992 |
| NTR-old | NTR2109 |
| Other | METC Universiteit Utrecht : 08/225 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A