The role of catecholaminergic neurotransmission in attention and cognition

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The aim of this (pilot) study is to investigate if stress affects memory and attention skills by impacting the dopamine and noradrenalinesystem.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON43560

Source
ToetsingOnline

Brief title
Catecholamines, attention and cognition

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
aandacht en leer problemen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: atomoxetine, cognition, Dopamine, Magnetic Resonance Imaging (MRI)

Outcome measures

Primary outcome

The primary outcome is the difference in fMRI activity (measurement of brain blood flow) during the attention/memory task between placebo and atomoxetine session in relation to cortisol, alpha-amylase, blood pressure, heart rate and mood after the mild stressor

Secondary outcome

Behavioural performance (reaction time, errors) on learning and attention tasks will be compared between placebo and atomoxetine session.

Study description

Background summary

Psychiatric disorders such as depression, psychosis and addiction are serve and costly illnesses. The causes that lead to psychiatric symptoms are not entirely clear, although it is well known that stress plays an important role in the development of psychiatric symptoms. It has been demonstrated previously that stress induces memory and attention problems (a key feature of psychiatric disorders) by lowering noradrenaline and dopamine in the brain. However, this evidence has been demonstrated in animal studies; such findings are strongly lacking in humans.

Study objective

The aim of this (pilot) study is to investigate if stress affects memory and attention skills by impacting the dopamine and noradrenalinesystem.

Study design

In a 1-hour session, we will once measure the effect of mild stress on psychological (mood) and physiological (cortisol and alpha-amylase) parameters

in 20 male participants. In the same 20 male participants, we will also measure memory and attention-related skills using 7 tesla MRI (30 min. non-invasive) and computerised tasks. Participants complete memory and attention-related tasks twice; once after placebo (a fake pill) and once after atomoxetine 60mg (oral; a safe challenge that temporarily increases noradrenaline and dopamine in the brain). This will happen according to a double-blind (researcher and participant) randomized cross-over design.

Intervention

During sessie 1, participant are subjected to a mild stress task. In session two and three, a non-invasive MRI measurement will be performed on a 7 tesla MRI system; once after placebo and once after 60mg atomoxetine.

Study burden and risks

* Participation takes time: one session of 1 hour, and two sessions of 3 hours.
* Taking a pil twice: once placebo, once atomoxetine
* Lying down in the MRI scanner for half an hour twice
* Performing on computer tasks twice.
* Filling in a questionnaire about mental health and lifestyle once

The risk of participation is deemed negligible, because atomoxetine is well tolerated. If there are any side effects, these are mild and temporary (please also see section 5.3 and 11 in the research protocol).

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Male
* No use of any psychopharmacological treatment at in the past or at time of inclusion.
* No presence of a physical/medical condition that may interfere with the study
* No contradiction for MRI
* Age between 18 and 30
* right handedness

Exclusion criteria

* Diagnosis of a psychiatric disorder (DSM-V)
* Diagnosis of a neurological disorder
* Very high (>30) or low (>18) BMI
* Current recreational drug use/dependence (CIDI)
* Current alcohol dependence (CIDI)
* High blood pressure (>150 systolic, >100 diastolic)
* Non-responders to the mild stressor in session 1

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-04-2016
Application type:	Amendment
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

ID: 24350

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL53913.068.15
OMON	NL-OMON24350