PREDICTING THE WIDE-RANGING EFFECTS OF ENHANCING DOPAMINE ON COGNITION

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON38150

Source
ToetsingOnline

Brief title
DOPAMINE AND COGNITION

Condition

- Cognitive and attention disorders and disturbances

Synonym
distractability, lack of motivation

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Veni grant,Human Frontiers;James McDonnell Foundation;Donders Centre for Cognitive Neuroimaging Principle Investigator

budget.

Intervention

Keyword: cognition, dopamine, individual differences

Outcome measures

Primary outcome

The current study will collect the following primary study parameters

Baseline measures:

Barratt Simplified Measure of Social Status (Average score)

Multidimensional Scale of Perceived Social Support (Average score)

Dominance scale (Average score)

The Beck Depression Inventory (Average score)

The Barratt Impulsiveness Scale (Average score)

The BIS/BAS (Behavioural Inhibition Scale/Behavioural Activation (BIS/BAS)

Scale (Average score)

The Daneman and Carpenter listening span test (Average score)

Outcome measures:

Social Learning (Beta value for personal learning)

Social Learning (Win-stay, lose-shift behaviour)

Social Learning (Perseveration)

Working memory (Accuracy and reaction time)

Motivation x activation reinforcement learning task (Pavlovian bias)

Probabilistic reversal learning (Lose-switch, win-stay behaviour)

Probabilistic reversal learning (Perseveration)

Pavlovian to Instrumental Transfer (Vigour changes upon Pavlovian stimuli)

Demand selection task task (Bias towards easy/difficult condition)

Secondary outcome

Secondary measures will also be collected for each task (see section 6.1.2 of

the research protocol (C1) for further details)

Study description

Background summary

It is known that adequate dopaminergic stimulation is important for many psychological functions including, memory, learning and social cognition. It is also known that dopamine levels can be increased by a number of pharmaceutical agents such as methylphenidate, and that such agents are associated with significant individual differences. At present our ability to predict individual differences in the effect of enhancing dopamine across a wide-range of tasks is limited.

Study objective

The current study aims to further our understanding of the relationship between baseline measures - such as impulsivity, working memory and social support - and the effects of enhancing dopamine (via methylphenidate administration) across a wide range of tasks. The results of this study will help make progress towards the development of a model which enables the effects of enhancing dopamine on various domains of cognition to be predicted from an individual's scores on a selection of baseline measures.

Study design

A within-subject, double-blind, placebo-controlled, design will be employed. All subjects will visit the Donders Centre for Cognitive Neuroimaging (DCCN) for two testing sessions that will last between 5 and 6 hours. On study day one, 50 subjects will receive oral capsules of 20mg methylphenidate and 50 subjects will receive oral placebo capsules. On study day two subjects will receive the capsule (methylphenidate or placebo) that they did not receive on study day one. Methylphenidate can be administered safely without any relevant risk of serious adverse events and has been approved for clinical use in the

Netherlands.

Subjects will be recruited via posters and from the Donders database of subjects who have expressed an interest in participating in research (sona-systems). The investigator will send an information brochure to subjects that respond to these adverts. Approximately one week after receiving the information brochure a member of the research team will contact the potential subject by phone or email to answer any questions they have and schedule an appointment. When subjects arrive at the Donders Centre on the day of testing they will be asked, by a member of the research time, for their written fully informed consent before taking part in any study related activities.

On study day one participants will first undergo a medical screening interview to ensure that they do not meet any of the exclusion criteria. Subjects will then complete a baseline measure of working memory, receive one oral capsule of either 20mg MPH or placebo, rest for approximately 1.5 hours, and then complete the battery of cognitive tests. On study day two, subjects will complete the same procedure, but without the medical screening interview; in this session subjects will receive the capsule (methylphenidate or placebo) that they did not receive on study day one.

Between study days subjects will have copies of a number of questionnaires emailed or posted to them. Questionnaires will take approximately 1 hour to complete.

Study burden and risks

Subjects will be asked to complete a battery of computerized tests after administration of methylphenidate or placebo. On the day preceding the drug session, subjects will have to adhere to some simple restrictions with respect to medication, alcohol and drug intake. Also, on the morning of each session, subjects will have to refrain from smoking and stimulant containing drinks. The most common side effect of taking methylphenidate is a headache (occurring in over 10% of people who take the drug). Other, less common, side effects include feeling dizzy, nauseous or anxious. However, our prior experience with administering methylphenidate has found that the drug is well tolerated by subjects. Considering the extensive exclusion criteria, the screening procedure, and constant monitoring of the subjects we do not expect (S)AE side effects. The consent discussion starts sufficiently in advance of the initiation of study-related procedures to allow potential subjects time to reflect on the potential benefits and risks and possible discomforts. Overall we believe that the risk associated with participation in this study can be regarded as minimal.

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

Healthy volunteers between 18 and 45 years of age

Exclusion criteria

Neuropsychiatric disorders; history of drug abuse; heart problems (see section 3.3 in research protocol (C1) for full list of exclusion criteria)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	30-01-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-05-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 26989
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47166.091.13
NTR-new	NL4411
NTR-old	NTR4653
OMON	NL-OMON26989

Study results

Date completed: 01-09-2014

Actual enrolment: 106

Summary results
Trial is onging in other countries