Effects of methylphenidate on language comprehension and creativity

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43672

Source
ToetsingOnline

Brief title
Methylphenidate, language & creativity

Condition

- Other condition

Synonym
out-of-the-box thinking, reading

Health condition

language& creativity in healthy controls

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO Spinoza Prize awarded to Peter Hagoort

Intervention

Keyword: creativity, dopamine, language comprehension, working memory

Outcome measures

Primary outcome

Primary study parameters will include task performance (e.g. accuracy, reaction times), electroencephalographic (EEG) measures, measures of baseline characteristics (e.g. working memory capacity, eye blink rate), subjective measures (e.g. self-report questionnaires, visual analogue scales) and physiological measures (e.g. heart rate, blood pressure).

Secondary outcome

not applicable

Study description

Background summary

Brain dopamine is known for its impact on prefrontal functions. A growing number of studies showed the effects of dopamine reuptake inhibitor methylphenidate on cognitive control, working memory and response inhibition. The methylphenidate effects on cognitive control and working memory likely have consequences for other cognitive domains such as language and creativity. However, there is no empirical evidence for such cross-domain effects. We therefore aim to fill the gap by investigating the effects of methylphenidate on language comprehension and creativity. It is also known that the impact of methylphenidate on prefrontal functions varies across individuals. The effects of methylphenidate on language comprehension and creativity might also relate to individual subjects* baseline characteristics such as working memory

capacity, eye blink rate and baseline creativity.

Study objective

Our primary objective is to investigate the effects of methylphenidate on language comprehension and creativity, and to link these effects with the effects of methylphenidate on working memory. Our secondary objective is to establish the relation between the methylphenidate effects and the cognitive baseline characteristics of individual subjects.

Study design

This study will use a within-subject double-blind placebo-controlled randomized crossover design. The subjects will receive either 20mg oral methylphenidate or placebo capsule in each session. Methylphenidate has been approved for clinical use in the Netherlands and the drug can be administered safely without any relevant risk of serious adverse events.

Study burden and risks

The subject will have to visit the laboratory site twice. At each visit they will have to complete a series of language, creativity and working memory tasks after receiving 20mg methylphenidate or placebo. On the day before each visit they will have to adhere to some simple restrictions regarding medication, alcohol and drug intake. In the morning of each visit they will have to refrain from smoking and stimulant-containing drinks. The most common side effects of methylphenidate include headache, dizziness, nausea and anxiety. However, previous studies have shown that the single dose of 20mg (or more) methylphenidate is well tolerated in healthy adults. Considering the extensive exclusion criteria, screening procedure and constant monitoring of the subjects, we do not expect serious side effects.

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 old

Exclusion criteria

History of neurological or psychiatric disorders; history of drug abuse; heart problems (see section 4.3 of the research protocol for a 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:	Recruiting
Start date (anticipated):	07-09-2016
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	09-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-01-2017
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: 28408
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51075.091.14
OMON	NL-OMON28408