The effects of vardenafil on cognition in healthy subjects; an EEG study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25199

Source
NTR

Brief title
Vardenafil and cognition: an EEG study

Health condition

cognition, EEG, vardenafil

cognitie, EEG, vardenafil

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

The main outcome is the behavioural score on the memory tests; the verbal learning task (VLT), the spatial memory task (SMT) and the continuous recognition memory task (CRMT).

Secondary, the event-related potentials during those tasks will be analyzed.

Secondary outcome

Other important outcomes are the behavioural scores on the Tower of London (TOL) and the Stroop task. In addition, visual and auditory evoked potentials (respectively VEPs and AEPs), which will give an indication of the role of vardenafil in information processing are important measures as well. Finally, the ratio (S2/S1) of the P50 is a measure of sensory gating.

Study description

Background summary

Research on the neurobiological foundations of memory and learning has shown that phosphodiesterase inhibitors increase the level of cGMP (cyclic Guanosine Monophosphate), which plays a role in the induction of hippocampal long-term potentiation (LTP). This is thought to be an important mechanism of learning and memory. It has indeed been found that the administration of phosphodiesterase type 5 (PDE-5) inhibitors improves memory performance in rats. So far, only a few studies have examined the effects of PDE-5 inhibitors on cognition in humans. The results of these studies, in which the PDE-5 inhibitor sildenafil was used, have been quite contradictory. Therefore, we decided to use vardenafil which is a more selective PDE-5 inhibitor than sildenafil, and as a result, more potent and has fewer side effects.
The primary objective is to examine whether vardenafil (a PDE-5 inhibitor) can improve the cognition of healthy young volunteers.
Secondary, we will assess the effects of vardenafil on electrophysiological correlates of cognition.

18 healthy males and females between 18 and 35 years of age will participate. They will be recruited via advertisements at Maastricht University and in the Observant (university paper). Furthermore, they will be selected out of a group of 40 subjects, based on their performance on a memory screening.

Participants will be treated with vardenafil 10 mg, vardenafil 20 mg, or a placebo. All treatments will be taken orally. The treatment order will be established by counterbalancing.

Study objective

We hypothesize that vardenafil improves cognition. This will be apparent as increased recall/recognition scores in a verbal and pictorial memory task, as well as percentage correct in a spatial memory paradigm.

Study design

- Three test days, which will be separated by a washout period of at least 7 days

Intervention

The study will be conducted according to a double-blind, placebo-controlled, 3-way cross-over design. Order of treatments (vardenafil 10 mg, vardenafil 20 mg and a placebo) will be balanced over three test days, which will be separated by a washout period of at least 7 days. The balancing of the treatment order will be accomplished by counterbalancing. There will be six different treatment orders, meaning that each order will be received by three participants.

Contacts

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Eligibility criteria

Inclusion criteria

1. Volunteers who are male or female,

2. 18 to 35 years of age,

3. Healthy (i.e. absence of all exclusion criteria),

4. Normal static binocular acuity (corrected or uncorrected),

5. Body mass index between 18.5 and 30,

6. Willingness to sign an informed consent,

7. Positive evaluation on the screening.

Exclusion criteria

1. Excluded will be those volunteers who suffer from or have a history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological or psychiatric illness.

2. Other exclusion criteria are excessive drinking (>20 glasses of alcohol containing beverages a week),

3. Pregnancy or lactation,

4. Use of medication other than oral contraceptives,

5. Use of recreational drugs from 2 weeks before until the end of the experiment,

6. Any sensory or motor deficits which could reasonably be expected to affect test performance.

7. Those volunteers who have a first-degree relative with a psychiatric disorder or a history of a psychiatric disorder will also be excluded.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-07-2008
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion Date:	28-03-2008
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	NL1217
NTR-old	NTR1262
Other	MEC : 08-3-011
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A