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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25199

Bron
NTR

Verkorte titel
Vardenafil and cognition: an EEG study

Aandoening

cognition, EEG, vardenafil

cognitie, EEG, vardenafil

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2008
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1217
NTR-old	NTR1262
Ander register	MEC : 08-3-011
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A