# Effects of vardenafil on cognition in healthy adults: an EEG study

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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.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32222

**Source**
ToetsingOnline

**Brief title**
Vardenafil and cognition

### Condition

- Other condition

**Synonym**
nvt

**Health condition**

geen aandoening

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cognition, Electrophysiology, Memory, Phosphodiesterase

## Outcome measures

### Primary outcome

The main endpoint is the behavioural score on the memory tests; the verbal learning task (VLT), the object relocation task (ORT) and the continuous recognition memory task (CRMT),. Secondary, the event-related potentials during those tasks will be analysed.

### Secondary outcome

Other important measures are the Tower of London (TOL) and the Stroop task. In addition, the 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.

### Study objective

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.

### Study design

The study will be conducted according to a double-blind, placebo-controlled, 3-way cross-over design.

### Intervention

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 burden and risks

The time investment for the participants will be around 13 hours in total, which is comprised of 1) screening (around 30 min), 2) medical assessment by questionnaire and medical checkup (around 1 hour), 3) training session in which the tasks will be practised (around 2 hours), and 4) three test sessions of around 3 hours, which include 45 minutes waiting. The day before a recording, the participants are not allowed to drink any alcohol and are asked to eat only nitrate-low food.

## 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

Male or female, 18 to 35 years of age, Healthy (i.e. absence of all exclusion criteria), normal static binocular acuity (corrected or uncorrected), Body mass index between 18.5 and 30, Willingness to sign an informed consent, Positive evaluation on the screening

## Exclusion criteria

A history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological or psychiatric illness. Other exclusion criteria are excessive drinking (>20 glasses of alcohol containing beverages a week), pregnancy or lactation, use of medication other than oral contraceptives, use of recreational drugs from 2 weeks before until the end of the experiment, and any sensory or motor deficits which could reasonably be expected to affect test performance. 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 |

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|---|---|
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-07-2008 |
| Enrollment: | 40 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Levitra |
| Generic name: | vardenafil |
| Registration: | Yes - NL outside intended use |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 24-04-2008 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

Approved WMO

| | |
|---|---|
| Date: | 16-09-2008 |
| Application type: | First submission |
| 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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2008-000785-23-NL |
| CCMO | NL21943.068.08 |