Effects of rivastigmine on biperiden-induced memory impairment in healthy adults: an EEG study

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

Summary

ID

NL-OMON31193

Source
ToetsingOnline

Brief title
Rivastigmine and memory

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: NWO

Intervention

Keyword: Acetylcholine, Electrophysiology, Memory

Outcome measures

Primary outcome

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

Secondary outcome

Another important parameter is the change in behavioural and brain response to the choice reaction time task, since this measures a possible sedative effect of the two drugs.

Study description

Background summary

Research on the neurobiological foundations of memory has shown that the neurotransmitter acetylcholine plays the most important role in memory processing. Furthermore, the cognitive enhancers used in Alzheimer*s disease contain cholinergic substances. So far, little research was performed to unravel in which way cognitive enhancers such as rivastigmine can improve memory in healthy participants with biperiden-induced cholinergic deficit. However, this may provide valuable information as to how the cholinergic system affects memory processing. In this study, we will clarify this issue.

Study objective

The primary objective is to examine whether a memory impairment as a result of biperiden treatment (cholinergic M1 antagonist) can be reversed by rivastigmine (a cholinesterase inhibitor). Secondary, we will assess the effects of biperiden and rivastigmine on electrophysiological correlates of memory.

Study design

The study will be conducted according to a double-blind, placebo-controlled, 4-way cross-over design.

Intervention

Participants will be treated with biperiden, rivastigmine, a combination, 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 15 hours in total, which is comprised of 1) medical assessment by questionnaire and medical checkup (around 1 hour), 2) training session in which the tasks will be practised (around 2 hours), and 3) four test sessions of around 3 hours, which include 1 hour waiting. The day before a recording, the participants are not allowed to drink any alcohol.

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, between 18 and 25 years of age, healthy (absence of exclusion criteria), normal static binocular activity, body mass index between 18.5 and 30, willingness to sign an informed consent.

Exclusion criteria

history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological or psychiatric illness, 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
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2008
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Akineton
Generic name:	Biperiden
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Exelon
Generic name:	Rivastigmine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	14-11-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-12-2007
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	EUCTR2007-004972-37-NL
CCMO	NL19605.068.07