Methylphenidate and the pathogenesis of apathy in dementia

Published: 03-07-2007
Last updated: 08-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON30740

Source
ToetsingOnline

Brief title
Methylphenidate and apathy

Condition

- Dementia and amnestic conditions

Synonym
lack of initiative; emotional blunting

Research involving
Human

Sponsors and support

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

Intervention

Keyword: apathy, dementia, Methylphenidate

Outcome measures

Primary outcome

Change in apathy score after the methylphenidate challenge (difference between before and after the challenge) compared to the change in score after the placebo condition as measured by the patient version of the Apathy Inventory (IA)

Secondary outcome

Change in cognitive and other behavioural scores after the methylphenidate challenge (difference between before and after the challenge) compared to the change in score after the placebo condition

* on the level of frontal related behaviour, as assessed by specific frontal related neuropsychological tests like the Verbal Fluency Test, the Stroop Colour Word Test and five tasks of the CANTAB.

* on the level of novelty seeking behaviour as assessed by a 15 minute observation of the patient.

Study description

Background summary

Apathy is the most frequent neuropsychiatric symptom in dementia. In addition, it is the most stressful symptom for primary caregivers and has the greatest

negative impact on the quality of the relationship between patient and caregiver. It is therefore of great importance to gather more knowledge regarding the pathogenesis of apathy in dementia. Little is known about neurochemical mechanisms of apathy, but recently, investigators have suggested that dopaminergic drugs may be useful for reducing apathy in dementia. Dopaminergic circuits have been related to self-reward and initiating aspects, and in this respect they are of interest for studies into the pathogenesis of apathy in dementia. Therefore, it is of importance to study whether dopaminergic markers are of influence on the development of apathy in dementia.

Study objective

The main objective of this project is to study the relationship between dopaminergic mechanisms and apathy in dementia. The related question, both theoretically and of direct relevance for daily practice, is whether patients with dementia are apathetic primary because problems of initiating or because of loss of capacities to interact. Is there evidence for deficient functioning of self-reward and initiation systems, as manipulated by administering a methylphenidate challenge, in dementia patients and apathy?

Study design

A randomized double-blind placebo-controlled within subjects design.

Intervention

All subjects receive a methylphenidate challenge task or a placebo condition. All subjects will receive a dose of 10 mg methylphenidate in the challenge condition.

Study burden and risks

The burden and risks associated with the present study are related to two visits on two separate days. Each day will start with the administration of a neuropsychiatric and neuropsychological investigation (2 hour) (clinical characteristics of the patients will be obtained only on the first day), observation of spontaneous behaviour (15 minutes), accordingly the methylphenidate challenge or placebo, and after 1.5 hours the outcome measures are repeated (around 1.5 hour). Methylphenidate is used in previous studies in patients with apathy and dementia without reporting of adverse events, so again burden and risks are expected to be minimal. Because the main objective is to study the pathogenesis of apathy in dementia, the inclusion of dementia patients in the present study is necessary.

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

-Dementia diagnosed according to the DSM-IV criteria for dementia
-Presence of a reliable informant
-Presence of apathy
-Capable to consent
-Informed consent

Exclusion criteria

-If living in a nursing home at the start of the study
-Patients without a reliable informant
-Concurrent psychiatric disease

-Presence of agitation, irritability, and/or psychotic symptoms
-Use of pharmacological medication
-Use of vasopressors
-Abuse of alcohol and drugs

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-12-2007
Enrollment:	37
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Methylphenidate
Generic name:	Ritalin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	03-07-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	23-07-2007
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	EUCTR2006-006625-83-NL
CCMO	NL16072.068.07