Influence on brain perfusion and metabolism through pharmacologic agents

Published: 30-10-2006
Last updated: 09-05-2024

In this study we would like to investigate whether cerebral perfusie and cerebral metabolism can be influenced with pharmacological agents in patients with MS and in healthy control persons. Cerebral perfusion and cerebral metabolism wil be measured...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON29781

Source
ToetsingOnline

Brief title
perfusie_pharma

Condition

- Demyelinating disorders

Synonym
multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebral metabolism, cerebral perfusion, cisapride, clenbuterol, magnetic resonance imaging, multiple sclerosis

Outcome measures

Primary outcome

- The difference in measures of cerebral perfusion before and after use of the

trial medication in and between the groups of patients and healthy control

persons

- The difference in measures of cerebral metabolism (as measured with MR

spectroscopy) in and between the groups of patients and healthy control persons

Secondary outcome

none

Study description

Background summary

The pathogenesis of progression in MS is unknown. Our research group has formulated the hypothesis that astrocytes play an important role in the pathophysiology of progression in MS. According to our hypothesis, astrocytic disfunction leads to a decreased energy supply to axons and to a disturbed cerebral microperfusion. It is not known whether cerebral perfusion and cerebral metabolism can be influenced with pharmacologic agents.

Study objective

In this study we would like to investigate whether cerebral perfusie and cerebral metabolism can be influenced with pharmacological agents in patients with MS and in healthy control persons. Cerebral perfusion and cerebral metabolism wil be measured with special MRI techniques.

Study design

Exploratory case control study

Study burden and risks

Medium burden for patients:
Three visits to the research centre of 2-3 hours duration:

- first visit: neurologic exam and baseline scan
- second visit: post-clenbuterol scan
- third visit: post-cisapride scan

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

1) a diagnosis of MS, according to the McDonald criteria with a secondary progressive disease

course and a disease duration of between ten and fifteen years
2) age 18-60 years
3) informed consent

Exclusion criteria

1) use of systemic corticosteroids in the eight weeks before inclusion into the trial
2) use of immunomodulatory treatments for MS
3) a history of cerebral pathology other than MS (cerebral infarct, cerebral haemorrhage, Parkinson's disease, Alzheimer's disease, cerebral vasculitis, brain absces)
4) diabetes mellitus, cardiac arrhytmia, prolonged qt time on ecg, pregnancy or breast feeding.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Prepulsid
Generic name:	Cisapride

Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Spiropent
Generic name:	Clenbuterol

Ethics review

Approved WMO Date:	30-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2006-004318-42-NL
CCMO	NL13976.042.06