Combined perfusion MRI and MR spectroscopy in multiple sclerosis

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Measures of cerebral perfusion and cerebral metabolism will be compared between patients with different disease courses of MS and healthy controls.Hereby we wish to answer the following questions:- Are cerebral energymetabolism and cerebral...

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

Summary

ID

NL-OMON30006

Source
ToetsingOnline

Brief title
MRI and MRS in MS

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: magnetic resonance imaging, magnetic resonance spectroscopy, multiple sclerosis, progression

Outcome measures

Primary outcome

Primary endpoints:

- The difference in measures of cerebral perfusion between the groups of RRMS,

SPMS, PPMS patients and healthy controls.

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

spectroscopy) between the groups of RRMS, SPMS, PPMS patients and healthy

controls.

- The correlation between measures of cerebral perfusion and cerebral

metabolism in the groups RRMS, SPMS, PPMS and healthy control persons.

Secondary outcome

Secondary endpoints:

- the correlation between clinical measures of disability with measures of

cerebral perfusion

- the correlation of clinical measures of disability with measures of cerebral

metabolism

Study description

Background summary

There are two disease courses in multiple sclerosis: (1) a form with relapses and remissions (relapsing remitting MS) and (2) a chronically progressive disease course.

Exacerbations are caused by focal inflammatory demyelinating lesions. Immunomosulatory treatments can reduce the number of relapses to some extent. The most important underlying mechanism of progression in MS is a diffuse axonal degeneration. The pathogenesis of this progressive axonal demise is unknown and there is no treatment for it.

With this study we would like to investigate the role of cerebral perfusion in the pathogenesis of progression in MS. Therefore we would like to measure brain metabolism and perfusion in healthy controls and patients with different disease courses of MS. Metabolism will be measured with 1H and 31P MR spectroscopy, cerebral perfusion will be measured with dynamic susceptibility contrast enhanced perfusion MRI.

Study objective

Measures of cerebral perfusion and cerebral metabolism will be compared between patients with different disease courses of MS and healthy controls.
Hereby we wish to answer the following questions:
- Are cerebral energymetabolism and cerebral perfusion decreased in MS patients in an early stage of the disease (before the start of the progressive phase)?
- Are metabolism and perfusion of the cerebral white matter related to each other?
- Are cerebral perfusion and cerebral metabolism related to the degree of disability as measured with clinical rating scales?

Study design

Exploratory case control study

Study burden and risks

Minimal burden participants:
- one non-invasive neurologic examination
- one MRI study

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

Inclusioncriteria patients:
- age 18-60 years
- diagnosis of multiple sclerosis according to the McDonald-criteria (McDonald et al., 2001).
- written informed consent;Inclusioncriteria controls:
- age eightteen and older
- written informed consent

Exclusion criteria

Exclusioncriteria patients:
- use of systemic corticosteroids in the eight weeks before start of the study
- use of immunomodulating therapies (interferon-ß, glatiramer acetate)
- a history of cerebral pathology other than MS (brain infarct, brain haemorrhage, Parkinson's disease, Alzheimer's disease, cerebral vasculitis, brain absces)
- Diabetes mellitus;Exclusiecriteria controls:
- a history of cerebral pathology (brain infarct, brain haemorrhage, Parkinson's disease, Alzheimer's disease, cerebral vasculitis, brain absces)
- Diabetes mellitus

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

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
CCMO	NL13857.042.06