Cerebral hypoperfusion in familiar amyloid polyneuropathy

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

Summary

ID

NL-OMON31535

Source
ToetsingOnline

Brief title
FAP-PET

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
familiar amyloid polyneuropathy, Systemic amyloidosis

Health condition

systemisch amyloïdose

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Onderzoeksbudget afdeling Neurologie;UMCG

Intervention

Keyword: cerebral perfusion, familiar amyloid polyneuropathy, positron emission tomography

Outcome measures

Primary outcome

Cerebral perfusion and metabolism measured with water-PET en FDG-PET.

Secondary outcome

Not applicable.

Study description

Background summary

Familiair amyloid polyneuropathy(FAP) is a form of systemic amyloïdosis, in which a broad diversity of organs is affected by accumulation of amyloidfibrils. One of the most important clinical manifestations of FAP is a combined sensory and motor polyneuropathy. In some patients with FAP cognitive disorders, thought to be due to accumulation of amyloidfibrils in the vesselwall. However, a MRI of metabolic PET-scan does not show pathological changes.
In a similar fashion accumulation of amyloidfibrils is found in the vesselwall of patients with Alzheimer's disease. Perfusion and metabolic positron emission tomography has shown a decreased perfusion and metabolism in the parietotemporal cortex. The hypotheses of another scientific research in Alzheimer's disease, conducted at the UMCG, is that the perfusion deficits run ahead of metabolic changes.
Therefore, it is hypothesized that pathological changes of the vesselwall lead to diminished perfusion and in turn to decreased metabolism in FAP patients with cognitive disorders.

Study objective

The goal of this study is to investigate the possible pathophysiology of cognitive disorders in patients with familiar amyloid polyneuropathy (FAP). Hypothesis: Familiair amyloid polyneuropathy patients with mild cognitive disorders show decreased cerebral perfusion, especially in the parietotemporal cortex, compared to patients without cognitive disorders.

Study design

After signing the consentform patients with familair amyloid polyneuropathy will be invited to the out-patient clinic of the department of Neurology (UMCG). At this visit a general physical and neurological examination together with cognitive screeningtests will be performed.
On the day of the positron emission tomography, after veneus cannulation of the patient, radio-active water will given intraveneusly. The scanwill take a mere 10 minutes. Together with the preparation in advanced and once the scan is finished the PET investigation does not take longer than one hour of the patients time.
The collected perfusiondata will be compared to the perfusional data from a database with healthy volunteers. Furhtermore, in the case where a FAP patient has already received a FDG-PET on clinical ground, a comparison between perfusion and metabolisme will be made.
The data will be analyzed on voxel-level with the Statistical Parametric Mapping (SPM) and compared to the data of healty volunteers.

Study burden and risks

According to the international and national radiation criteria for patients the radiation dose for this study falls in the category 'mild risk' (BS2001, IRCP62).

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

Patients with familiar amyloid polyneuropathy.

Exclusion criteria

- prior stroke, contusion or other neurological or psychiatric condition which more probable to cause cognitive deficits
- prior exposure to radiation in the setting of scientific research
- pregnancy
- age <18years

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	10
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	NL20491.042.08