Quantitative MR evaluation of vascular steal in AVM patients: a comparative study on normal subjects and on the longitudinal impact of endovascular treatment in AVM patient concerning neurocognition

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Ethical review	-
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON31972

Source
ToetsingOnline

Brief title
Measurements of (effects of) cerebrovascular steal in AVM patients

Condition

- Central nervous system vascular disorders

Synonym
arteriovenous malformation, vessel malformation of the brain

Research involving

Human

Sponsors and support

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

Intervention

Keyword: arteriovenous malformation, magnetic resonance, neurocognition, vascular steal

Outcome measures

Primary outcome

Primary study parameters are:

- Cambridge Cognitive Examination (CAMCOG) total score controlled for mood/neuropsychiatric status (to evaluate global cognitive functioning),

- cerebral blood volume, cerebral blood flow, mean transit time (to evaluate brain perfusion/vascular steal),

- quantitative MR parameters (e.g. T1 and T2 relaxation times) (to evaluate structural abnormalities in brain parenchyma)

- correlation between (changes in) neurocognitive functioning, (changes in) brain perfusion and (changes in) quantitative MR parameters, before and after endovascular treatment.

- predictive value of pre-operative perfusion and quantitative MR parameters with regard to treatment effect on neurocognitive funtion in patiens

Secondary outcome

Secundary study parameters are:

- Obliteration rate of the AVM after endovascular treatment.

Study description

Background summary

Title:
Quantitative MR evaluation of vascular steal in AVM patients: a comparitive study on normal subjects and on the longitudinal impact of endovascular treatment in AVM patients concerning neurocognition.

Background of the study:
In patients with cerebral arteriovenous malformations (AVMs) neurocognitive dysfunction can occur, which has received little attention so far. The pathophysiological substrate of neurocognitive dysfunction is not clear, some have postulated that a high flow volume shunted through an AVM fistula may induce a decrease in cerebral perfusion pressure in surrounding brain tissue, the so called 'vascular steal' phenomena, resulting in symptomatic cerebral ischemia with development of neurocognitive deficits. Evaluation of these - perhaps reversible - structural changes in cerebral tissue surrounding an AVM can be performed by quantitative and hemodynamic MR imaging.

Study objective

In this study we will evaluate if neurocognitive disturbances, vascular steal and structural changes in cerebral tissue surrounding an AVM are present in AVM patients. Further, we will evaluate if these aforementioned alterations are correlated and subject to change after endovascular treatment. Finally, the results of this study may indicate that neurocognitive dysfunction may be used to plan treatment in AVM patients, in addition to the occurence of hemorrhage, headaches and epilepsy.

Study design

20 AVM patients and 20 control subjects will be included in this pilot study. Patients who are considered eligible for endovascular treatment will be asked to participate in this study. Control subjects will be matched to patients according to age and years of education. Patients and control subjects will undergo a neuropsychological test battery (duration appr. 3 hours) and will be scanned for appr. 45 minutes (total MR investigation time 60 minutes). In patients, neuropsychological testing and MR examination will be repeated 3 months after endovascular treatment. In control subjects, neuropsychological testing will be repeated to evaluate possible learning effects. The MR investigation consists of qualitative MR sequences, MR perfusion and quantitative MR measurements. A total of appr 10 sequences will be performed. No contrast agent will be administered in control subjects. Patients and control subjects will receive ear-protection and head-phones for communication

purposes.

Study burden and risks

No side effects of MRI have been proven and MRI is generally assumed to be completely safe. MRI is the standard investigation in the diagnostic work-up of AVM patients before endovascular treatment and is standardly being used to evaluate the effect of endovascular treatment. For the purpose of this study protocol, MR perfusion and quantitative MR measurements will be added to these standard sequences, these measurements will take appr. 20 - 25 minutes. The duration of these extra MR investigations is relatively short. Duration of the neuropsychological test battery will take appr. 3 hours.
No contrast agent will be administered in control subjects. The MRI examination in control subjects is non-invasive and the risk to the control subject is negligible. All procedures have been tested by the researchers involved and during the examination experienced MR personnel will operate the scanner. Control subjects will be screened for claustrophobia. The control subject will be protected against scanner noise. The control subject can withdraw from this study at any time during the 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

AVM patients with age between 18 and 55 years, considered eligible for endovascular treatment, with cerebral AVMs confined to a single hemisphere (the non-affected hemisphere will be used to assess within-patient control values of hemodynamic and quantitative MR parameters). Informed consent will be obtained from all patients.
Control subjects will be matched to patients according to age and intelligence level.
Inclusion criteria for control subjects:
1. healthy male or female subject with age between 18 and 55 years.
2. voluntary participation
3. having given their written informed consent
4. willing to accept use of all anonymized data, including publication, and the confidential use and storage of all data

Exclusion criteria

Patients will be excluded from the investigation if they 1. manifest dural or multiple AVMs; 2. present with intracerebral haematomas, since the presence of intracerebral hematoma may interfere with preoperative neuropsychological testing. Further, resorption of the haematoma probably affects neurocognitive function (and distinction of this effect from treatment effect will pose problems, if possible at all). 3. suffer from any other central nervous system anomaly; 4. have a medical history of chronic drug or alcohol abuse.
Exclusion criteria for control subjects:
1. having a current brain or vascular disease
2. claustrophobia
3. having metal implants or metal objects on the body which cannot be removed
4. mental of physical status that is incompatible with the proper conduct of the study
5. being under medication that may affect neurocognitive function

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Not available

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	NL22995.058.08