Cerebral perfusion, measured by Arterial Spin Labeling (ASL) perfusion MRI, in relation to outcome in children and young adults with ischaemic stroke

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31120

Source
ToetsingOnline

Brief title
Brain perfusion in relation to outcome in young stroke patients

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
ischaemic stroke; stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Het Wilhelmina Onderzoeksfonds zal een deel van het onderzoek financieren. Tevens is het onderzoek in portefeuille bij de Catherijne stichting.

Intervention

Keyword: ASL perfusion MRI, ischaemic stroke, outcome, young stroke

Outcome measures

Primary outcome

Primary outcome measure: functional outcome, defined as *good* or *poor*.

Standardized outcome measures for stroke will be used (Paediatic Stroke Outcome

Measure (PSOM)), modified Rankin Scale (mRS) and Quality of Life outcome

scales).

Secondary outcome

Secondary outcome measure: recurrent stroke during follow-up

Study description

Background summary

Causes and risk factors of stroke in children and young adults are different from those in adults. Atherosclerosis of large arteries is extremely rare in children and most children and young adults with arterial ischaemic stroke (AIS) suffer from non-atherosclerotic arterial disease (arteriopathy). Childhood arteriopathies may be progressive as in moyamoya disease, or non-progressive as in dissection and inflammatory arteriopathies (transient cerebral arteriopathy and post-varicella arteriopathy).
Arteriopathic stroke has a relatively high recurrence rate, depending on the cause of stroke (6 - 42%, mainly within the first year). Neurological outcome is poor in the majority of children.
Possible treatment options for patients with arterial ischaemic stroke include corticosteroids, anticoagulants, and in moyamoya disease neovascularization surgery.

Unfortunately, the prediction of stroke outcome and the course of the arteriopathy is difficult in the acute stage of stroke. Knowledge of cerebral perfusion deficits in different causes of young stroke could potentially help identifying patients who are at risk of poor outcome or stroke recurrence. Information on risk factors of poor outcome and stroke recurrence may eventually guide treatment decisions.

Study objective

The objective of the study is to assess whether in young patients with arteriopathic stroke perfusion abnormalities in non-infarcted brain are associated with the type and course of arteriopathy and stroke outcome in terms of functional recovery and recurrence risk.
Furthermore, we would like to assess whether diffusion-weighted MRI (DWI) changes in descending corticospinal tracts of the brain are associated with motor outcome in children and young adults.

Study design

In the retrospective part of the study, 50 children and young adults (between 6 and 50 years of age) will be approached. All patients have been treated in the UMCU for anterior circulation stroke caused by non-atherosclerotic arteriopathy, between Januari 2000 and August 2007.
Patients will visit the UMC Utrecht once and will undergo conventional MRI, MR angiography (MRA), and ASL perfusion MRI in the chronic stage of their disease. If children will be restless during the MR investigation, they will be excluded (< 7 years of age). General anesthesia will not be given to patients, solely for the purpose of the study.
Functional stroke outcome wil be assessed as good or poor, using a two-item questionnaire, a standardized outcome measure for children (PSOM), and the modified Rankin Scale for young adults. The rate of recurrent stroke will be determined.

In the prospective part of the study, 30 children and young adults (between 1 month and 50 years of age) will be included. In patients who present to the UMC Utrecht with anterior circulation stroke, caused by non-atherosclerotic arteriopathy, MRI and MRA will be performed as part of the diagnostic investigations in the acute stage of stroke. For this research project ASL perfusion will be added to the scan protocol (5 minutes extra) in children that do not need to be sedated for MR investigation. Furthermore, diffusion-weighted imaging (DWI) of the corticospinal tracts will be studied. In children, imaging is performed 6 and 12 months after stroke, as part of the normal follow-up. Again, ASL will be added to the scanprotocol in children > 6 years of age. In adults MR imaging is not routinely done in the follow-up period. For this research project MR imaging will be performed at 6 and 12 months after stroke. Functional stroke outcome and stroke recurrence rates will be determined at a

follow-up duration of 1 year.

Study burden and risks

Retrospective part of the study: patients will visit the UMC Utrecht once. Conventional MRI, MR angiography (MRA), and ASL perfusion MRI will be performed and functional stroke outcome wil be assessed by filling in a questionnaire. This will take about two hours in total. Children will not be sedated or brought under anesthesia for the purpose of the study. Children who cannot undergo MR scanning without general anesthesia will be excluded.

Prospective part of the study: functional stroke outcome and stroke recurrence rates will be determined at a follow-up duration of 1 year (one hour twice). MRI and MRA will be performed as part of the diagnostic investigations in the acute stage of stroke. In most patients the cause of stroke is not evident prior to the first imaging procedure. Therefore ASL perfusion will be added to the scan protocol in the acute phase of stroke in all patients with suspected anterior circulation stroke that do not need to be sedated for MR investigation. In children with AIS, imaging is performed 6 and 12 months after stroke as part of the normal follow-up. If children do not need to be sedated for follow-up MR imaging, ASL perfusion will be performed (5 minutes extra). There are no extra risks for participating in this study. In all patients DWI changes of the corticospinal tracts will be studied.
For adult patients who don't need to undergo routine clinical follow-up imaging, MRI (including DWI), MRA and ASL perfusion will be performed 6 and 12 months after stroke for this research project.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

For patients in the retrospective cohort:
- Children at the age of 7 years - 18 years and adults between 18 and 50 years of age
- Patients can undergo MR imaging on the 3 Tesla MR scanner without the necessity for anaesthesia (children > 6 years of age)
- Patients treated in the UMC Utrecht for arterial ischaemic stroke in the anterior cerebral circulation between January 2000 and August 2007
- Proven non-atherosclerotic arteriopathy at vascular imaging < 3 months after the onset of symptoms
- Informed consent must be given by the patient and/or parents.;For patients in the prospective cohort:
- Children at the age of 1 month - 18 years and adults between 18 and 50 years of age
- Patients are able to undergo MR investigation within 72 hours after the onset of symptoms and after 6 and 12 months
- Arterial ischaemic stroke (AIS) in the anterior cerebral circulation
- The cause of stroke is an underlying non-atherosclerotic arteriopathy
- Informed consent must be given by the patient and/or parents.

Exclusion criteria

Contra-indications for MRI
(claustrophobia; pacemaker or automatic defibrillator; some mechanical heart valves; swan-ganz catheter; some aneurysm clips; gastrointestinal clips; cochlear implant; metal object in eye; dental prosthesis with magnetic attachment; hip prosthesis and metal hipnails of more than 50 cm; hydrocephalus- or insulinpump; uncovered skin; medicine patch; piercing)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2008
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	11-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL16846.041.07