MR Imaging of cerebral blood flow and autoregulation in patients with steno-occlusive vertebro-basilar artery disease.

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The primary objective will be to assess whether cerebrovascular reactivity is impaired in patients with steno-occlusive disease of the vertebrobasilar artery .

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

Summary

ID

NL-OMON36475

Source
ToetsingOnline

Brief title
VICTOR

Condition

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

Synonym
ischaemic cerebral stroke; stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial spin labeling, cerebral autoregulation, cerebral blood flow, MRI

Outcome measures

Primary outcome

The primary outcome is CVR measured with MR imaging at 3 Tesla using administration of vasodilatory challenge medication to induce hemodynamic stress.

Secondary outcome

Secondary outcomes include cerebral blood flow (CBF) and CVR measured in the visual cortex, and differences in CBF and CVR between the recently symptomatic and asymptomatic patients.

Study description

Background summary

In patients with ischaemic stroke and steno-occlusive disease of the vertebrobasilar artery it is difficult to assess which patients are at risk for future stroke and should be treated with an endovascular or surgical procedure. An important parameter that can predict such events is the cerebrovascular reactivity, the vasodilatory response of the cerebral resistance vessels. The global increase of cerebral blood flow under conditions of hemodynamic stress is a measure of the cerebrovascular reactivity.

Study objective

The primary objective will be to assess whether cerebrovascular reactivity is impaired in patients with steno-occlusive disease of the vertebrobasilar artery .

Study design

This is a single centre cross-sectional study at the UMC Utrecht, comparing asymptomatic patients and recently symptomatic patients with steno-occlusive

vertebrobasilar artery disease.

Study burden and risks

Risks of participation are associated with undergoing an MRI examination and administration of vasodilatory challenge medication. Both associated risks are well investigated and can be minimized according to our exclusion criteria. Patients do not benefit individually. However results of this investigation may prove to be valuable in understanding risk of reoccurrence of stroke in patients with and without steno-occlusive vertebrobasilar artery disease.

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

18 years or older.
Patients with ischaemic stroke or TIA in the perfusion territory of the vertebo-basilar arteries.
In case of stroke: a clinically stable situation.

Exclusion criteria

Significant and symptomatic stenosis of the carotid arteries.
Pregnancy or possible pregnancy.
Implanted stent(s).
Severe liver or renal dysfunction.
Addison*s disease.
Allergic reaction for sulfonamides.
Cor pulmonale / heart failure (class III-IV) according to the NYHA classification.
Longobstruction / emfysema.
Primary hyperaldosteronisme.
Fenytoïne, primidon and/or fenobarbital use.
Japanese and Indian subjects or subjects of Japanese descent.
Impossibility to undergo MRI (claustrophobia, metal objects in or around the body).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-09-2012
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Diamox
Generic name:	Acetazolamide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	02-05-2011
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
EudraCT	EUCTR2010-022875-70-NL
CCMO	NL33961.041.10