thrombogenicity and platelet reactivity as risk factors for postoperative microemboli signals in patients undergoing carotid endarterectomy

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON32409

Source
ToetsingOnline

Brief title
MES (Micro Embolism Signal)

Condition

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

Synonym
arteriosclerosis, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atherosclerosis, coagulation, Endarteriectomy, stroke

Outcome measures

Primary outcome

The amount (mean and peak) of MES, measurd with TCD, starting from the first

postoperative hour, during a period of 3 hours.

Secondary outcome

a recurrent ipsilateral ischaemic stroke, or death within a period of 1 year

starting from the day of the operation

Study description

Background summary

Atherosclerosis is one of the most important causes of morbidity and mortality in western society. This major problem merits particular attentention with regard to research, in order to optimise the prevention, the care and the treatment of tis disease.
An ischaemic stroke is often the result of atherosclerosis in the carotid artery. The diagnostics and treatment of a recent stroke or a recent TIA is partly based on the degree of stenosis found in the carotid artery. A surgical intervention, named carotid endarterectomy, using the current indication criteria (stenosis > 70%) has prooved to be effective in the reduction of recurrent strokes. However, of all patients undergoing this intervention, 2-7% develops a stroke in the postoperative phase. Nowadays transcranial doppler sonographie is often used postoperatively in order to detect micro-embolisms (MES), because in literature there is a growing evidence of a correlation between the amount of MES and the occurence of a stroke.
Both coagulation parameters and platelet reactivity are considered to play an important role in the formation of such micro-embolisms. The determination of these parameters will result in a beter identification of patients at risk of

developping postoperative stroke.

Study objective

The objective of this study is to predict which patients will develop MES after carotid endarterectomy, using different coagulation parameters and platelet function tests, so in the future these patients will be indentified early. Identification of this subgroup may lead to a more adequate and early intervention for these patients.

Study design

100 patients undergoing carotid endarterectomy will be included in the study. Before the surgical intervention coagulation parameters and platelet function will be determined using different laboratory test. Durin operation one more blood samplewill be obtained,10 minutes after the injection of heparin. After the operation patients will be monitored using TCD, starting from the first postoperative hour during 3 hours. Subsequently we will investigate whether or not there is a correlation between the markers and the amount of postoperative MES. Also correlations between markers and the occurence of stroke will be investigated. There will be a follow-up period of 21 year.

Study burden and risks

There are no risk related to TCD. All the risk of these study will be related to the venepunctures. Bruises resulting from the venepuncture is a common complication, but not harmful. Also thrombophlebitis might occur, although this is rare complication.

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 an ischemic stroke or TIA (first episode or recurrent disease) AND:
an ipislateral stenosis of the carotid artery for which operation of the carotid artery is indicated.
Patients need to have an adequate transtemporal window for TCD monitoring og the ateria cerebri media
Age > 18 year and < 90years

Exclusion criteria

proven coagulopathies
pregnancy
active infections
chronic inflammatory diseases
anti-phospholipid syndrome
active malignancy
recent cardiovascular intervention (< 3 months)
cardiac arrythmias
postradiation stenosis of the carotid artery
patients with exlusion criteria for MRi can participate in the study, they will not undergo MRI investigations. Exclusion criteria are: feroomagnetic implans, introcular iron splinters, vascular clips and claustrophobia.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-12-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL23681.068.08
Other	TC = 1472