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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25062

Source
Nationaal Trial Register

Brief title
MES-study

Health condition

stroke
carotic endarterectomy
blood coagulation
platelet reactivity
beroerte
carotis endarteriectomie
bloedstolling
plaatjesfunctie

Sponsors and support

Primary sponsor: MUMC
Source(s) of monetary or material Support: MUMC + a profileringsfondsaanvraag was admitted.

Intervention

Outcome measures

Primary outcome

Amount of MES signals (mean and SD) during TCD monitoring start from the first postoperative hour during a period of 3 hours in relation to thrombogenicity and platelet reactivity

Secondary outcome

- Postoperative stroke in realtion to thrombogeniticity and platlet reactivity during 1 year follow-up

- Postoperative stroke (asymptomatic) during 7 days follow-up starting from operation day, detected by MRI

Study description

Background summary

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 1 year.

Study objective

High thrombogenicity and platelet reactivity are risk factors for postoperative micro-emboli on transcranial doppler and postoperative strokes.

Study design

T1= operation day -1: blood sample

T2= during operation: blood sample

T3= first 3 hours after the operation: TCD

T4= operation day +7: MRI cerebrum

T5= operation day + 365: clinical follow-up

Intervention

1) 2 bloodsamples at T1 and T2 for Callibrated Automated Thrombogram and for coagulation factors and platet function tests.

2) Transcranial Doppler sonography at T3. The amount of MES are measured during a period of 3 hours starting from the first postoperative hour.

3) MRI at T4

Contacts

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Eligibility criteria

Inclusion criteria

1. 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.

2. Patients need to have an adequate transtemporal window for TCD monitoring og the ateria cerebri media

Exclusion criteria

1. Proven coagulopathies

2. Pregnancy

3. Active infections

4. Chronic inflammatory diseases

5. Anti-phospholipid syndrome

6. Active malignancy

7. Recent cardiovascular intervention (< 3 months)

8. Cardiac arrythmias

9. Postradiation stenosis of the carotid artery

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-01-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL1412
NTR-old	NTR1472
Other	23681 : MEC08-3-061
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A