

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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25062

Bron

Nationaal Trial Register

Verkorte titel

MES-study

Aandoening

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

Ondersteuning

Primaire sponsor: MUMC

Overige ondersteuning: MUMC + a profileringsfondsaanvraag was admitted.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 sample will 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 occurrence of stroke will be investigated. There will be a follow-up period of 1 year.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

1) 2 bloodsamples at T1 and T2 for Callibrated Automated Thrombogram and for coagulation

2 - Thrombogenicity and platelet reactivity as risk factors for postoperative microe ... 15-06-2025

factors and platelet 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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with an ischemic stroke or TIA (first episode or recurrent disease) AND:
an ipsilateral 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 of the arteries of the cerebri media

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 arrhythmias
9. Postradiation stenosis of the carotid artery

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	100

Type:

Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1412
NTR-old	NTR1472
Ander register	23681 : MEC08-3-061
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A