Changes in middle cerebral artery pulsatility during the first days after carotid endarterectomy.

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To gain understanding about the changes in intracranial hemodynamics after carotid endarterectomy. To improve the early detection of an imminent hyperperfusion syndrome.

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

Summary

ID

NL-OMON30610

Source
ToetsingOnline

Brief title
MCA Pulsatility after carotid endarterectomy

Condition

- Central nervous system vascular disorders
- Bone and joint therapeutic procedures

Synonym
hyperperfusion

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: IAG subsidie (vanuit Europese Unie),Neuromon BV; Assen,RUG Houdster Mij.

Intervention

Keyword: carotid, endarterectomy, hemodynamics, TCD

Outcome measures

Primary outcome

measurement of PaR value for the right and left middle cerebral artery on day 0

peroperatively and day 0-3 postoperatively in relation to the mean arterial

blood pressure and the end-tidal carbon dioxide.

Secondary outcome

none

Study description

Background summary

During carotid endarterectomy a significant stenosis is removed from the lumen of the internal carotid artery. This will allow a better conduction of blood volume and of the blood pressure wave over the carotid arteries. Most patients have little problem with this increase in perfusion pressure. In some, however, the perfusion pressure cannot sufficiently be overcome by vascular resistance and the blood pressure wave may travel into the cerebral capillaries at risk of causing cerebral oedema, haemorrhage, swelling and, ultimately, death. This is called a hyperperfusion syndrome.
Customary, all patients who receive carotid endarterectomy at the Martini Ziekenhuis Groningen are monitored by dailyTCD examination for the early detection of an imminent hyperperfusion syndrome. The present investigation wishes to expand this protocol by a simultaneous recording of the electrocardiogram, of the carbon dioxide content of exhalation gas and of the blood pressure. These extra signals allow the calculation of a so-called PaR-value, which gives better information on intracranial hemodynamics than TCD alone.

Study objective

To gain understanding about the changes in intracranial hemodynamics after carotid endarterectomy. To improve the early detection of an imminent

hyperperfusion syndrome.

Study design

Instead of the usual follow up with a TCD examination on day 0 preoperatively and on day 0-3 postoperatively, the study is designed to record simultaneously with the TCD signal the electrocardiogram, the end-tidal carbond dioxide and the arterial blood pressure. All signals are recorded non-invasively.
Combining the TCD signal with the ABP signal will allow the calculation of the so-called pulsatile apparent resistance or PaR, a parameter that has been shown to give better information on intracranial hemodynamics than TCD alone.

Study burden and risks

Instead of 5 times a TCD examination during the first 3 postoperative days after carotid endarterectomy the subjects will undergo 5 times a PaR measurement during the first 3 postoperative days. The usual TCD examination takes about 30 minutes, whereas the PaR measurement takes roughly 60 minutes (30 min. preparation; 30 min. actual measurement).

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 receiving carotid endarterectomy who have sufficiently echolucent temporal windows allowing blood flow velocity measurements of the intracranial arteries by means of transcranial Doppler (TCD).

Exclusion criteria

insufficient temporal windows for TCD investigation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2007
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	27-02-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL14702.030.06