DEVELOPMENT, IMAGING AND QUANTIFICATION OF VULNERABILITY IN HUMAN CAROTID PLAQUES.

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To identify morphological and molecular characterisations of resected carotid plaques. And to determine biomarkers in serum. The emphasis will lie on inflammatory biomarkers such as Cathepsines and matrix metalloproteinases. Also it will be examined...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON30835

Source ToetsingOnline

Brief title plaque vulnerability

Condition

• Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

unstable plaque, vulnerable plaque

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen Source(s) of monetary or material Support: afdeling Heelkunde UMCG

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Intervention

Keyword: bio imaging, carotid, plaque, vulnerable

Outcome measures

Primary outcome

Endpoints will be:

- the find of biomarkers where symptomatic patients are compared with

asymptomatic patients

- the find of certain proteins at proteomics (or hedgehog signals) which can be

correlated to both the presence of the plaque, and (preoperative) symptoms of

the patient.

- showing a detectable signal at fluorescence, a relation will be sought

between the intensity of the signal and the vulnerability of the plaque

(related to previously detected biomarkers and patient symptoms).

Secondary outcome

nvt

Study description

Background summary

Currently, the indication for a carotid endarterectomy is set on the grade of stenosis. The morphology of the carotid plaque plays no role in the indication for surgery. It is likely that a vulnerable plaque will sooner become symptomatic than a stable plaque, independent of grade of stenosis. With conventional imaging techniques, plaque morphology is not adequate to determine.

Study objective

To identify morphological and molecular characterisations of resected carotid plaques. And to determine biomarkers in serum. The emphasis will lie on 2 - DEVELOPMENT, IMAGING AND QUANTIFICATION OF VULNERABILITY IN HUMAN CAROTID PLAQUE ... 13-05-2025 inflammatory biomarkers such as Cathepsines and matrix metalloproteinases. Also it will be examined to what extent fluorescence indicators are detectable in the resected plaques.

Study design

Pre- and postoperative, blood will be drawn from the patient. The carotisplaque will surgically be removed. The material will be examined on biomarkers, among other things cathepsines and matrix metalloproteinases. Also, with bio-optical agents, fluorescence will be determined in the resected carotid plaques.

Study burden and risks

The carotid plaque will be resected surgically in the usual manner. Blood will be drawn twice, by venous puncture.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

3 - DEVELOPMENT, IMAGING AND QUANTIFICATION OF VULNERABILITY IN HUMAN CAROTID PLAQUE ... 13-05-2025 Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

asymptomatic stenosis of the internal carotid artery, stenosis >80% symptomatic stenosis of the internal carotid artery, stenosis >70%

Exclusion criteria

none

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):	01-05-2007
Enrollment:	35
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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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 CCMO **ID** NL17259.042.07