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Severe atherosclerosis in the neck arteries (carotid stenosis) - an observational study

Submission date 21/03/2024	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 07/05/2024	**Overall study status** Ongoing	[X] Statistical analysis plan [_] Results
Last Edited 03/09/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Carotid stenosis is a common cause of ischemic stroke. This study assesses many issues, but the two most important are:
1. What is the risk of stroke when patients with symptomatic near-occlusion (very severe stenosis) do not undergo carotid surgery?
Several previous studies have shown that patients with symptomatic near-occlusion do not need carotid surgery, why guidelines recommend conservative treatment. However, the way near-occlusion was diagnosed in these studies is too difficult to do in routine health care. Researchers have just developed a new diagnostic tool - phase contrast MRI - that makes it easy to set the diagnosis. They will now study what happens when this method is implemented in routine health care.
2. What is the best preoperative medical treatment?
It is unclear if intensive or less intensive antiplatelet medication is preferable before carotid surgery. Intensive is known to be better for many other causes of stroke than carotid stenosis and this is most likely also true for carotid stenosis. Guidelines state that either is acceptable. We use the intensive treatment and will compare the risk of stroke with studies that use less intensive treatment.

Who can participate?
Patients treated for carotid stenosis

What does the study involve?
The study involves an extra blood sampling and more follow-up.

What are the possible benefits and risks of participating?
The risks and benefits of participating are very minor. Most of the aspects of the study happen in the clinic and are the same whether one participates in the study or not. All are treated according to what is considered to be the state of the art.

Where is the study run from?
Region Västra Götaland (Sweden)

When is the study starting and how long is it expected to run for?
October 2023 to December 2041

Who is funding the study?
Region Västra Götaland (Sweden)

Who is the main contact?
Dr Elias Johansson, elias.johansson@neuro.gu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
UCC protocol 2024-03-18

Study information

Scientific Title
Sahlgrenska Carotid Cohort

Acronym
SCC

Study objectives
Observational study with several goals. The primary goals are:
1. Assess long-term risk of stroke when systematically detecting and conservatively treating symptomatic carotid near-occlusion
2. Assess the impact of dual antiplatelet therapy on the risk of preoperative stroke before carotid endarterectomy

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 02/04/2024, Etikprövningsmyndigheten (Box 2110, Uppsala, 750 02, Sweden; +46 (0) 10 475 08 00; registrator@etikprovning.se), ref: 2024-00221-01

Study design
Observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Diagnostic, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Symptomatic carotid stenosis or carotid web

Interventions
The study assesses the risk of vascular events, radiology findings and blood biomarkers in patients treated at or referred to the neurology clinic at Sahlgrenska, Gothenburg, Sweden.

Notable aspects are:
1. The researchers introduce phase-contrast MRI in routine practice to detect near-occlusion and treat patients with symptomatic near-occlusion conservatively (i.e. systematically implement guideline-recommended management).
2. They use dual antiplatelet therapy before surgery and will compare prognosis with previous (completed) studies where single antiplatelet therapy was used.
3. They draw and store blood for biomarker analyses.
4. There is a 10-year follow-up.

Intervention Type
Other

Primary outcome(s)
1. Recurrent preoperative stroke, assessed clinically, from presenting event until carotid surgery or stenting
2. Postoperative stroke or death, assessed clinically, within 30 days of carotid surgery or stenting
3. Long-term vascular events including, stroke, TIA, myocardial infarction, new-onset angina, new-onset heart failure, new-onset symptomatic peripheral artery disease, arterial revascularization and vascular death. Assessed for 10 years by annual review of medical records and diagnosis registry searches at 5 and 10 years.

Key secondary outcome(s))
1. Diagnostic: Flow measured in internal carotid artery and several comparison arteries on preoperative phase contrast MRI
2. Diagnostic: Artery diameters in the stenosis, internal and external carotid arteries measured on preoperative CT-angiography
3. Diagnostic: Flow velocities measured in common carotid artery, the stenosis and distal to the stenosis on preoperative ultrasound
4. Prognostic: All ipsilateral ischemic events (stroke, retinal artery occlusion, TIA and amaurosis

fugax) recorded between the presenting event and surgery/stenting
5. Prognostic: All-type stroke recorded preoperatively between presenting event and surgery /stenting
6. Pathophysiological: Collateral status assessed by flow direction assessment of intracerebral arteries on preoperative phase contrast MRI
7. Pathophysiological: Collateral status assessed by appearance (normal/small/not seen) of intracerebral arteries on preoperative CT angiography
8. Pathophysiological: Velocity and flow profiles of the common carotid artery, the stenosis and distal to the stenosis on preoperative ultrasound
9. Pathophysiological: Intraoperative measurements of stump pressure, flow, cerebral oxygenation (NIRS)

Completion date
31/12/2041

Eligibility

Key inclusion criteria
1, 2 or 3 + 4 and 5:
1. Suspicion of symptomatic ≥50% carotid stenosis or occlusion
2. Symptomatic <50% stenosis (on all exams) that is considered for carotid surgery or stenting anyway, usually due to repeated symptoms despite best medical therapy
3. Carotid web, both symptomatic and asymptomatic
4. Treated at or referred to the neurology clinic at Sahlgrenska University Hospital
5. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
150 years

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
02/05/2024

Date of final enrolment
31/12/2031

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hosptial
Blå Stråket 7
Gothenburg
Sweden
43541

Sponsor information

Organisation
Region Västra Götaland

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Government

Funder Name
Västra Götalandsregionen

Alternative Name(s)
Region Västra Götaland, Västra Götaland Regional Council, Västra Götaland region, Västra Götalandsregiona, VGR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

Data is stored in the research group and can be made available upon reasonable request.
The name and email address of the investigator/body who should be contacted for access to the datasets: Dr Elias Johansson (elias.johansson@neuro.gu.se).
The type of data that will be shared: All data (clinical, radiological and biomarkers) is subject to sharing.
Dates of availability: From study start and onwards.
Whether consent from participants was required and obtained: Consent is required and obtained.
Comments on data anonymization: Shared data will be pseudonymised.
Any ethical or legal restrictions: Data will be shared after completing of a material transfer agreement (MTA) and collaborative research agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/05/2024	No	No
Statistical Analysis Plan			07/05/2024	No	No