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Combining maximized ("proximal") brain protection in percutaneous treatment of carotid artery narrowings with stents designed to trap the atherosclerotic plaque: a study of brain injury

Submission date
28/12/2025

Recruitment status
Recruiting

Registration date
30/12/2025

Overall study status
Ongoing

Last Edited
30/12/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Prior evidence shows that micronet-covered stents implanted under distal cerebral protection (intraprocedural filter) significantly reduce cerebral embolism, as depicted by diffusion-weighted magnetic resonance cerebral imaging, compared to conventional carotid stent use under filter protection. Proximal cerebral protection by transient flow reversal/cessation in the carotid artery subjected to stent-assisted revascularization reduces cerebral embolism compared to filter protection. The combined effect of a micronet-covered stent and proximal cerebral protection has not been determined in a clinical study.

Who can participate?
Patients aged 18-100 years with clinically symptomatic or asymptomatic carotid artery stenosis, undergoing neuroprotected transfemoral carotid artery stenting as per international guidelines and indication confirmed by the local NeuroVascular Team recommendation.

What does the study involve?
The study involves consecutive patients undergoing carotid revascularization with the micronet-covered stent implantation under proximal cerebral protection, non-invasive cerebral imaging using diffusion-weighted magnetic resonance prior to the procedure and 48 hours after the procedure. There is no additional risk associated with post-procedural diffusion-weighted cerebral imaging, as it is contrast-free. Cerebral imaging, using computed tomography or magnetic resonance imaging, is routinely performed prior to carotid artery stenting and it may be performed after the procedure.

What are the possible benefits and risks of participating?
Possible benefits include potential detection of cerebral embolism that, if significant, may warrant increased patient surveillance.

Diffusion-weighted magnetic resonance imaging does not require any contrast agent use and it is safe. There are no known risks to participants in relation to cerebral imaging using diffusion-weighted magnetic resonance in the absence of contraindications to magnetic resonance imaging (NB. contraindications to magnetic resonance imaging are an exclusion criterion in this study).

Where is the study run from?
The study is managed, as part of academic research, by the Jagiellonian University, Department of Cardiac and Vascular Diseases, Poland.

When is the study starting and how long is it expected to run for?
December 2023 to June 2026.

Who is funding the study?
The Jagiellonian University Medical College, Poland.

Who is the main contact?
Piotr Musialek, MD DPhil - Principal Investigator, pmusialek@szpitaljp2.krakow.pl

Contact information

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Public, Scientific

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Scientific, Principal investigator

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Additional identifiers

Jagiellonian University Medical College Academic grant number
K/ZDS/007819

Study information

Scientific Title
PROXimal cerebral protection and CGUARD micronet-covered stent atherothrombotic plaque insulation to reduce cerebral embolism in carotid artery stenting: a diffusion-weighted magnetic resonance imaging study

Acronym
PROXGUARD

Study objectives
To determine the incidence and magnitude of cerebral embolism, as detected by diffusion-weighted magnetic resonance imaging, in transfemoral carotid stenting employing micronet-covered (CGuard) stents and maximized intraprocedural cerebral protection ("proximal" protection).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/10/2022, Bioethical Committee of the Jagiellonian University (ul. Skawinska 8, Krakow, 31-066, Poland; +48 124332739; krystyna.zalewa@uj.edu.pl), ref: 1072.6120.286_2022

Study design
Prospective single-centre observational longitudinal study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Prevention of cerebral embolism related to carotid revascularisation

Interventions
Observation (detection) of cerebral embolism, as depicted by diffusion-weighted magnetic resonance imaging, in consecutive patients with symptomatic or asymptomatic carotid stenosis undergoing transfemoral carotid artery stenting with micronet-covered stent implantation under proximal cerebral protection.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Proximal cerebral protection devices applicable through transfemoral arterial access, Micronet-covered plaque-insulating carotid stents

Primary outcome(s)
1. Incidence of any new ipsilateral cerebral embolism measured using cerebral diffusion-imaging magnetic resonance scanning at 48 hours

Key secondary outcome(s))
1. Number and volume of any new ipsilateral cerebral embolism measured using cerebral diffusion-imaging magnetic resonance scanning at 48 hours

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Clinical criteria
1. Consecutive patients 18-100 years old accepted for CAS following neurological consultation and qualification for the procedure according to international guidelines.
2. The target lesion is a "de novo" atherosclerotic lesion
3. More than 6 months of life expectancy
4. Suitable clinical conditions for performing DW-MRI
5. Written informed consent approved by the Ethics Committee
6. Subject agrees to all required follow-up procedures and visits

Angiographic criteria
1. Symptomatic (transient ischemic attack, stroke, or amaurosis fugax within the last six months on the ipsilateral side of the stenosis) with carotid stenosis ≥50% as diagnosed by angiography using NASCET methodology, or
3. Asymptomatic patient with carotid stenosis ≥80% as diagnosed by angiography using NASCET methodology

Procedural criteria
1. Procedure involves the use of proximal cerebral protection ("Tailored" consecutive-patient CAS)
2. Procedure involves use of micronet-covered stent(s) (consecutive patients)
3. Feasibility to perform cerebral MR (DW) imaging

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Clinical criteria
1. Currently enrolled in another investigational device or drug study that has not completed the study or that clinically interferes with the current study endpoints
2. Recent surgical procedure within 30-days before or planned surgery within 30-days after the stenting procedure
3. Hepatic active disease (bilirubin> 35 mmol / l) or renal insufficiency (serum creatinine > 2.5 mg /dL or
glomerular filtration rate <60 ml / min)
4. Recent evolving acute stroke within 30-days of study evaluation
5. Myocardial infarction within 72 hours before carotid stenting procedure (CK-MB > three times normal)
6. Female patients of childbearing potential or known to be pregnant
7. Any known factor for potential stroke other than carotid stenoses, such as atrial fibrillation or atrial flutter (paroxysmal, permanent or persistent) or thrombophilia
8. Patient on VKA or new oral anticoagulants
9. Patients with coagulopathies
10. Any known stroke with the primary cause other than carotid artery stenosis
11. History of severe disabling stroke according to the modified RANKIN scale > 4
12. Patient has an intracranial aneurysm or arteriovenous malformation
13. Chronic heart failure III-IV NYHA functional class
14. Chronic or decompensated right ventricular failure
15. Polyvalent drug allergy
16. Sharp infringement of cerebral circulation
17. Serious occlusive disease of the peripheral arteries, which could interfere with the intervention and installation of the introducer sheath
18. The main carotid artery disease is not atherosclerosis (for example, vasculitis, traumatic lesions, radiation stenosis, fibromuscular dysplasia)
19. States impeding the performance of MRI
20. Lack of consent

Angiographic criteria
1. Total occlusion of the ipsilateral carotid artery
2. Pre-existing stent in the ipsilateral carotid artery OR the contralateral carotid artery that

extends into the aortic arch
3. Severe lesion calcification restricting stent deployment
4. >50% stenosis of the CCA proximal to target vessel
5. Known mobile plaque in the aortic arch
6. Lesion length exceeding 30 mm

Date of first enrolment
18/12/2023

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Poland

Study participating centre
Jagiellonian University Dept. of Cardiac & Vascular Diseases
St. John Paul II Hospital
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Sponsor information

Organisation
Jagiellonian University

ROR
https://ror.org/03bqmcz70

Funder(s)

Funder type
Not defined

Funder Name
Uniwersytet Jagielloński Collegium Medicum

Alternative Name(s)

Jagiellonian University Medical College

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available, upon reasonable request, from the Principal Investigator, Adam Mazurek, mazurekadam@yahoo.pl

IPD sharing plan summary
Available on request