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Testing new neck artery stents designed to safely trap atherosclerotic plaque and heal the artery

Submission date 14/12/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/12/2025	**Overall study status** Ongoing	
Last Edited 17/12/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Stent healing, as assessed by strut coverage, is a key parameter for optimizing the duration of "double" antiplatelet therapy (DAPT) in patients after stent implantation. Data on the micronet stent healing are lacking.
The aim of this study is to evaluate the strut coverage of MicroNET-covered CGuard stents by optical coherence tomography (OCT) at 1-3 months after implantation.

Who can participate?
Consecutive patients implanted with the micronet-covered stent (CGuard) in the carotid artery, who have indication to another (staged) endovascular intervention performed at 1, 2, or 3 months after the index carotid artery treatment

What does the study involve?
The study involves assessment of stent strut coverage using intravascular Optical Coherence Tomography ("an intravascular light transducer camera") imaging. OCT is routinely used as the modality of choice to evaluate stents.

What are the possible benefits and risks of participating?
Patients may benefit from identifying lack of stent healing or strut malapposition; this may trigger appropriate treatment.
Possible risks are associated with target vessel cannulation and contrast injection. However, in the study patients, the vascular access, catheterisation and contrast are, anyway, indicated and performed for a concomitant endovascular intervention.

Where is the study run from?
The study is run from a university research center, experienced in carotid and other endovascular interventions and in OCT imaging. (Jagiellonian University, Poland)

When is the study starting and how long is it expected to run for?
The study started in November 2024 and is expected to run till 31 December 2026.

Who is funding the study?
The study is funded by a research grant from the Jagiellonian University (Poland)

Who is the main contact?
Piotr Musialek, MD DPhil
Jagiellonian University Professor of Cardiovascular Medicine

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Piotr Musialek

ORCID ID
https://orcid.org/0000-0001-9300-4833

Contact details
80 Pradnicka St
KRAKóW
Poland
31-202
+48 126143399
pmusialek@szpitaljp2.krakow.pl

Additional identifiers

Protocol serial number
N41/DBS/001562

Study information

Scientific Title
Healing Profile of the micronet-covered AtheRomA-isolating carotid stents Deployed for optimIsed Guard against cerebral embolisM: Optical Coherence Tomography Study

Acronym
PARADIGM-OCT

Study objectives
To evaluate the strut coverage of MicroNET-covered CGuard stents by optical coherence tomography (OCT) at 1-3 months after implantation.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 20/11/2024, Bioethical Committee of the Jagiellonian University (Skawinska 8, Krakow, 31-066, Poland; +48 124332739; joanna.plucinska@uj.edu.pl), ref: 10726120286_2024

Study design
Single-centre prospective observational longitudinal study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Prevention of stroke in patients with carotid atherosclerosis treated with an innovative stent type

Interventions
In patients treated with micronet-covered stents for primary or secondary stroke prevention of carotid-related stroke, Optical Coherence Tomography (OCT) observation of stent coverage will be carried out at the point of another endovascular treatment performed at 1, 2 or 3 months after stent implantation.

Intervention Type
Other

Primary outcome(s)
Percentage of struts covered at 1, 2, or 3-months after stent implantation measured using Optical Coherence Tomography (OCT)

Key secondary outcome(s))
Percentage of struts malapposed at 1, 2, or 3-months after stent implantation measured using Optical Coherence Tomography (OCT)

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Consecutive patients implanted with the micronet-covered stent (CGuard) in the carotid artery, who have indication to another (staged) endovascular intervention performed at 1, 2, or 3 months after the index carotd artery treatment.

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
1. Lack of indication to staged endovascular treatment following idex carotid artery stenting with the Micronet-covered stent
2. Lack of consent

Date of first enrolment
02/12/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Poland

Study participating centre
Jagiellonian University Dept. of Cardiac & Vascular Diseases
St. John Paul II Hospital
80 Pradnicka St.
Krakow
Poland
31-202

Sponsor information

Organisation
Jagiellonian University Medical College

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 curent study will be available upon reasonable request from the Principal Investigator (pmusialek@szpitaljp2.krakow.pl)

IPD sharing plan summary
Available on request