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Local anesthesia for carotid artery surgery

Submission date 04/12/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/02/2024	**Overall study status** Completed	
Last Edited 03/11/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Carotid endarterectomy (CEA) is a surgical procedure designed to treat carotid artery disease, specifically the narrowing or stenosis of the carotid arteries (internal carotid stenosis), which are major blood vessels in the neck that supply blood to the brain. The goal of the procedure is to remove the atherosclerotic plaque that has built up within the carotid artery and to restore normal blood flow to the brain.
This study examines the effectiveness of plexus anesthesia versus general anesthesia for carotid endarterectomy procedures. We have adopted plexus anesthesia as our primary approach since January 2023, and this study presents a detailed evaluation of the initial 50 consecutive cases. We carefully considered both advantages and potential drawbacks to assess the long-term viability of plexus anesthesia for patients with significant and symptomatic carotid stenosis. Additionally, we provide insights into the patients' perspectives and experiences during carotid endarterectomy under plexus anesthesia.

Who can participate?
Patients aged over 18 years with symptomatic internal carotid stenosis

What does the study involve?
Death rates, serious adverse (neurological) events, complications and conversions of plexus anesthesia are collected from electronic patient files.

What are the possible benefits and risks of participating?
This is a retrospective study so there is no further burden for the participants. All data are anonymized and encoded.

Where is the study run from?
Euregio-Klinik (Germany)

When is the study starting and how long is it expected to run for?
December 2023 to October 2025

Who is funding the study?
Euregio-Klinik (Germany)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Plexus anesthesia introduced as the standard technique for carotid endarterectomy in a regional teaching hospital: the first 50 consecutive cases

Study objectives
Is introduction of plexus anesthesia for carotid endarterectomy patients in a regional teaching hospital possible within literature based complication rates?

Ethics approval required
Ethics approval not required

Ethics approval(s)
The board of the Ärztekammer Niedersachsen, Hannover, Germany have stated that no further ethical permission is needed for this study as the data collected has been anonymized in such a way that the person concerned cannot or can no longer be identified

Study design
Retrospective consecutive case series

Primary study design
Observational

Study type(s)
Efficacy, Quality of life, Other

Health condition(s) or problem(s) studied
Plexus anesthesia for carotid endarterectomy patients

Interventions
All symptomatic carotid endarterectomy patients are already operated on and encoded, all pre-, peri- and postoperative data codes will be used. Data is accessible in electronic patient files after informed consent of the Medical Ethical Board in Hannover has been obtained.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Mortality collected from electronic patient files from operation date (in 2023) to 31/10/2023
2. Serious adverse (neurological) events collected from electronic patient files from operation date (in 2023) to 31/10/2023

Key secondary outcome(s))
Complications and conversions of plexus anesthesia collected from electronic patient files from operation date to 31/10/2023

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Symptomatic internal carotid stenosis (>50%)
2. Adult (>18 years)

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
Previous ipsilateral internal carotid stenosis

Date of first enrolment
01/01/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Germany

Study participating centre
Euregio Hospital
Albert-Schweitzerstrasse 10
Nordhorn
Germany
48527

Sponsor information

Organisation
Euregio-Klinik

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Euregio-Klinik

Results and Publications

Individual participant data (IPD) sharing plan
IPD storage in a non-public and password-accessible computer. The datasets generated during and/or analysed during the current study are not expected to be made available due to the privacy laws in Germany. Moreover, the codes are not traceable to real patient data anymore after this was double-checked.

IPD sharing plan summary
Not expected to be made available, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes