

Local anesthesia for carotid artery surgery

Submission date 04/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/02/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/02/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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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Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Other, Quality of life, Efficacy

Participant information sheet

Not applicable (retrospective study)

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 measure

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

Secondary outcome measures

Complications and conversions of plexus anesthesia collected from electronic patient files from operation date to 31/10/2023

Overall study start date

01/12/2023

Completion date

01/10/2025

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

50

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

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Sponsor information

Organisation

Euregio-Klinik

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.euregio-klinik.de>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Euregio-Klinik

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed vascular surgery journal. The findings will be presented following the guidelines outlined in the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement, which offers a structured framework for reporting observational studies.

Intention to publish date

30/06/2025

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

Stored in non-publicly available repository, Not expected to be made available