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Carotid artery stenting during endovascular treatment of acute ischemic stroke

Submission date 05/12/2022	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/01/2023	**Overall study status** Ongoing	
Last Edited 18/08/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off. Approximately 1 in 5 patients suffering stroke have a narrowed carotid artery. It is not yet known if early treatment to insert a tube (stent) into the narrowed artery to hold it open and prevent future stroke is worth the difficulties associated with such treatment.

Who can participate?
Patients with acute ischemic stroke with a CT-angiography-proven intracranial LVO in the anterior circulation (ICA, A1, M1 or M2) as well as an ipsilateral cervical carotid artery tandem lesion of presumed atherosclerotic origin with a stenosis >50% or an ipsilateral acute proximal internal carotid artery occlusion who are treated with EVT according to the guidelines.

What does the study involve?
Patients will be randomly allocated to receive either a carotid artery stent immediately after suffering a stroke, or to treatment as usual.

What are the possible benefits and risks of participating?
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All patients are being treated with EVT according to the local guidelines. The patients allocated to the intervention group will undergo CAS during EVT, which carries a risk of cerebral hyperperfusion syndrome and subsequent intracerebral hemorrhage. The potential benefits of immediate CAS during thrombectomy include: an improvement of cerebral blood flow during and after EVT. A second benefit is a lower risk of recurrent stroke in the first 14 days compared to the deferred treatment strategy. A third benefit of immediate CAS is that the patient does not need a second invasive treatment (carotid revascularization surgery (CEA or CAS) during the rehabilitation period which again carries some risk of complications. At last, the immediate CAS approach is likely to reduce health care costs.

Where is the study run from?
The study will be coordinated by the University Medical Center Groningen in the Netherlands and by the University Hospital Leuven in Belgium. 26 centres (9 in Belgium and 17 in the Netherlands) will participate.

When is the study starting and how long is it expected to run for?
November 2022 to November 2026

Who is funding the study?
The study is part of the COllaboration of New TReatments of Acute STroke (CONTRAST) consortium (https://www.contrast-consortium.nl).
The study is funded by the BeNeFIT funding members (ZonMw/KCE) (the Netherlands)

Who is the main contact?
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Study website
https://cases-trial.eu/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06511089

Secondary identifying numbers
Nil known

Study information

Scientific Title
Carotid Artery Stenting during Endovascular treatment of acute ischemic Stroke: a randomized multicenter clinical trial in patients with acute ischemic stroke and carotid artery stenosis undergoing endovascular treatment

Acronym
CASES

Study objectives
Immediate carotid artery stenting is non-inferior compared to a deferred treatment of carotid artery stenosis/occlusion in patients with large vessel occlusion in the anterior circulation treated with endovascular thrombectomy.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 19/06/2023, Medische Ethische toetsingscommissie Erasmus MC Rotterdam (Postbus 20403000 , Rotterdam, CA, Netherlands; +31 10-70 34428 ; metc@erasmusmc.nl), ref: NL79046.078.23 (MEC-2023-0131)

2. Approved 19/06/2023, Ethics Committee Research UZ/KU Leuven (UZ Leuven, Herestraat 49, Leuven, B 3000 , Belgium; +32 16 34 86 00; ec@uzleuven.be), ref: B3222022001112. (S65073)

Study design
Randomized multicenter clinical trial with a PROBE design and a non-inferiority design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Acute ischemic stroke in patients with large vessel occlusion in the anterior circulation and a concommitant high grade ipsilateral carotid artery stenosis or occlusion of presumed atherosclerotic origin..

Interventions
Patients with an ipsilateral high grade carotid artery stenosis or occlusion of presumed atherosclerotic origin and an proximal intracranial large vessel occlusion in the anterior circulation will be randomized using a web-based randomization tool to immediate carotid artery stenting or deferred treatment strategy of carotid artery stenosis.

In the intervention group, the cervical carotid artery lesion will be treated with a stent during the EVT (just before or directly after
intracranial thrombus removal), the control group will be treated according to the national guidelines with carotid endarterectomy of carotid artery stenting (for patients with non-disabling stroke) or medical management alone (for patients with severe disabling stroke).

Follow up at 90 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Stroke-related disability measured using the Modified Rankin Scale (mRS) Score at 90 days after stroke onset.The mRS score will be assessed by stroke research personnel by telephone interview, blinded for the treatment allocation

Secondary outcome measures
1. NIHSS score at 24 hours and day 5-7, or at discharge (Medical examination)
2. Adequate recanalization after EVT (TICI 2b or higher) (Review of performed imaging)
3. Final infarct volume on brain CT at 24 hours (Review of performed imaging)
4. Arterial occlusive lesion (AOL) score on CTA at 24 hours (Review of performed imaging)
5. Any stroke within 90 days (Obtained from medical records)
6. Recurrent ipsilateral TIA/ischemic stroke within 90 days

7. Carotid artery re-occlusion at 24 hours and 90 days (Review of performed imaging)
8. Mortality at 90 days (Obtained from medical records)
9. Quality of life (EQ5D-5L) questionnaire at 90 days

Overall study start date
15/11/2022

Completion date
15/11/2026

Eligibility

Key inclusion criteria
1. Acute ischemic stroke due to proximal intracranial occlusion in the anterior circulation (intracranial ICA, M1, proximal M2) on the CT angiography
2. Stenosis >50% according to the NASCET criteria16 or initial occlusion of the ipsilateral cervical carotid artery of presumed atherosclerotic origin on baseline CT angiography
3. Eligible for EVT according to the guidelines: EVT within 6 hours of onset or EVT between 6-24 hours after onset based on perfusion CT imaging selection (conform current guidelines)
4. Baseline National Institute of Health Stroke Scale (NIHSS) score ≥2
5. Age >18 years
6. Written informed consent (deferred consent)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Any intracranial hemorrhage
2. Cervical carotid artery stenosis or occlusion with other causes than presumed atherosclerosis (e.g. carotid artery dissection, floating thrombus, carotid web)
3. Any exclusion criterion for EVT according to the guidelines
4. Pre stroke disability (defined as a modified Rankin Scale score >2)
5. Recent gastro-intestinal or urinary tract hemorrhage (<6 weeks)
6. Recent severe head trauma (<6 weeks)
7. Recent infarction on baseline brain CT in the same vascular territory (<6 weeks)
8. Known allergy to aspirin and/or clopidogrel
9. Pregnancy

Date of first enrolment
19/06/2023

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
Belgium

Netherlands

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University Medical Center Groningen
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Hospital/treatment centre

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Funder(s)

Funder type
Government

Funder Name
BeNeFIT call funding member (ZonMw and KCE)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
15/11/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request after central review by the "Data Access Writing Committee" from the CONTRAST consortium.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/02/2025	18/08/2025	Yes	No