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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 [_] 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 15/07/2024	**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?
Dr M. Uyttenboogaart, m.uyttenboogaart@umcg.nl

Study website
https://cases-trial.eu/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Maarten Uyttenboogaart

ORCID ID
http://orcid.org/0000-0002-6934-4456

Contact details
UMC Groningen
Hanzeplein 1
Groningen
Netherlands
9713 GZ
+31 50 3612400
m.uyttenboogaart@umcg.nl

Type(s)
Principal Investigator

Contact name
Prof Robin Lemmens

ORCID ID
http://orcid.org/0000-0003-3374-1502

Contact details

UZ Leuven
Herestraat 49
Leuven
Belgium
3000
+32 16 34 42 80
robin.lemmens@uzleuven.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil Known

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

Study participating centre
University Medical Center Groningen
Hanzeplein 1
Groningen
Netherlands
9713 GZ

Study participating centre
University Hospital Leuven
Herestraat 49
Leuven
Belgium
3000

Study participating centre
Amsterdam University Medical Center
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Study participating centre
Erasmus Medical Center Rotterdam
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015 GD

Study participating centre
Leiden University Medical Center
Albinusdreef 2
Leiden
Netherlands
2333 ZA

Study participating centre
Maastricht University Medical Center
P. Debyelaan 25
Maastricht
Netherlands
6229 HX

Study participating centre
Utrecht University Medical Center
Heidelberglaan 100
Utrecht
Netherlands
3584 CX

Study participating centre
Isala Zwolle
Dokter van Heesweg 2
Zwolle
Netherlands
8025 AB

Study participating centre
Haaglanden Medisch Centrum
Lijnbaan 32
Den Haag
Netherlands
2512 VA

Study participating centre
Haga Medisch Centrum
Els Borst-Eilersplein 275
Den Haag
Netherlands
2545 AA

Study participating centre
Rijnstate ziekenhuis
Wagnerlaan 55
Arnhem
Netherlands
6815 AD

Study participating centre
Catharina Ziekenhuis Eindhoven
Michelangelolaan 2
Eindhoven
Netherlands
5623 EJ

Study participating centre
Amphia Ziekenhuis
Molengracht 21
Breda
Netherlands
4818 CK

Study participating centre
Medisch Spectrum Twente
Koningstraat 1
Enschede
Netherlands
7512 KZ

Study participating centre
Noordwest Ziekenhuisgroep
Wilhelminalaan 12
Alkmaar
Netherlands
1815 JD

Study participating centre
Albert Schweitzer ziekenhuis
Albert Schweitzerplaats 25

Dordrecht
Netherlands
3318 AT

Study participating centre
Radboud University Medical Center
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6525 GA

Study participating centre
Sint Antonius Ziekenhuis
Koekoekslaan 1
Nieuwegein
Netherlands
3435 CM

Study participating centre
AZ Sint Jan
Ruddershove 10
Brugge
Belgium
8000

Study participating centre
Hopital Erasme
Lenniksebaan 808
Bruxelles
Belgium
1070

Study participating centre
Universitair Ziekenhuis Gent
Corneel Heymanslaan 10
Gent
Belgium
9000

Study participating centre
Civil Hospital Marie Curie
Chau. de Bruxelles 140
Charleroi
Belgium
6042

Study participating centre
UZ Brussel
Laarbeeklaan 101
Jette
Belgium
1090

Study participating centre
AZ Groeninge
President Kennedylaan 4
Kortrijk
Belgium
8500

Study participating centre
CHU Liège
Avenue de l'Hôpital 1
Liège
Belgium
4000

Study participating centre
Universitair Ziekenhuis Antwerpen
Drie Eikenstraat 655
Edegem
Belgium
2650

Study participating centre
Elisabeth Tweesteden Ziekenhuis
Hilvarenbeekse Weg 60
Tilburg
Netherlands
5022 GC

Study participating centre
UCL Saint-Luc
Hippokrateslaan 10
Brussel
Belgium
1200

Sponsor information

Organisation
University Medical Center Groningen

Sponsor details
Hanzeplein 1
Groningen
Netherlands
9713 GZ
+31 50 3616161
dlrvb@umcg.nl

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/EN

ROR
https://ror.org/03cv38k47

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