Carotid Artery Stenting during Endovascular treatment of acute ischemic Stroke (CASES) – study protocol for a multicenter randomized clinical trial

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Background & aims

Tandem occlusions are seen in approximately 20% of patients undergoing endovascular treatment (EVT) for stroke due to intracranial large vessel occlusions (LVOs). Variation in clinical practice exists regarding the timing of the management of these lesions. Immediate carotid artery stenting (CAS) during EVT could improve cerebral blood flow, reduce the risk of early stroke recurrence and avoid a second procedure (carotid endarterectomy [CEA] or CAS). However, dual antiplatelet therapy is required in order to prevent in-stent thrombosis which could lead to an increase in hemorrhagic complications, arguing in favor of delaying the management to a later time point. The aim of this study is to assess the efficacy and safety of an immediate strategy with CAS in patients with tandem lesions undergoing EVT.

Design

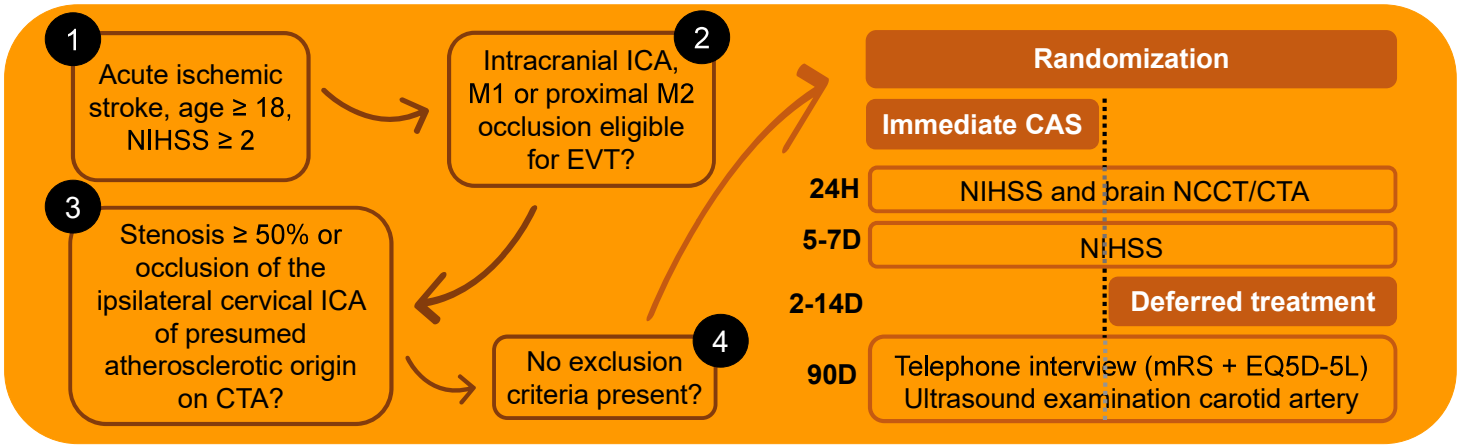
CASES is a phase 3 international multicenter randomized clinical trial with open-label treatment and blinded outcome assessment (PROBE design) and a non-inferiority design. Patients with a CT-angiography proven intracranial LVO in the anterior circulation and a symptomatic ipsilateral proximal carotid artery stenosis (>50%) or occlusion of presumed atherosclerotic origin will be randomized to either immediate CAS during EVT or to a deferred treatment strategy with CEA or CAS within two weeks or best medical management alone according to the current guidelines and depending on the functional recovery of the patient. A total of 600 patients will be included in 26 participating centers in the Netherlands and Belgium. Enrollment is expected to start in June 2023.

Outcomes

The primary endpoint is functional outcome at 90 days, assessed by the ordinal score of the modified Rankin Scale (mRS). Secondary outcomes include excellent functional outcome (mRS 0-1), good functional outcome (mRS 0-2), stroke severity measured with the National Institutes of Health Stroke Scale at 24 hours and at 5-7 day, infarct volume at 24 hours, recurrence of ischemic events, carotid re-occlusion, symptomatic intracranial haemorrhage, mortality and the quality of life at 90 days.

Summary

This study will provide high-quality data from a randomized controlled trial on the efficacy and safety of immediate CAS in patients undergoing endovascular treatment for acute ischemic stroke due to a tandem lesion.



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Disclosures

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