

Angioplasty and Stenting versus medical treatment in patients with symptomatic intracranial artery stenosis: a randomized controlled trial and a preference cohort

ACTRN12615000759594

Status	RECRUITING
Phase	Phase 2
Sponsor	Fuzhou General Hospital of Nanjing Command, PLA and clinical medical college of Fujian medical university
Enrollment	198 participants

Plain Language Summary

This study is for people who have had strokes or mini-strokes caused by a narrowed artery inside the brain. Researchers are comparing two treatments: a procedure to open the narrowed artery using a small balloon and a stent (a tiny wire tube), versus strong medicines alone. The goal is to find out which approach better prevents future strokes.

You may be eligible if:

- You are between 18 and 70 years old
- You have had a stroke or mini-strokes caused by a narrowed artery in the brain (70–99% blockage)
- The narrowed section is 15 mm or shorter and the artery is at least 2 mm wide
- Brain scans show reduced blood flow in that area
- You are able to give informed consent

You may NOT be eligible if:

- You cannot receive general anesthesia or angiography
- You have had a major brain bleed or large stroke recently
- You had a heart attack in the past 30 days
- You are pregnant or have childbearing potential without a negative pregnancy test
- You have a non-atherosclerotic cause for your artery narrowing (such as sickle cell disease or vasculitis)
- You have already had a stent placed in that artery

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (6)

- Patients aged from 18 to 70 years.
 - Complaints of a Symptomatic ICAS: a history of recurrent transient ischemic attacks or an ischemic stroke within 1 year owing to a stenosis from 70% to 99% in an internal carotid artery, middle cerebral artery, vertebral artery, or basilar artery.
 - A length less than or equal to 15mm of a stenosis in the target vessel and a vessel size greater than or equal to 2mm.
 - Hypoperfusion in the territory of the target vessels, which is determined by CT or MRI in 14 days before stenting.
 - CT or MRI scans show no massive cerebral infarction (beyond half of the MCA territory), intracranial hemorrhage, epidural or sub-dural hemorrhage, and intracranial brain tumor.
- ... and 1 more (see full listing online)

Exclusion (16)

- Not able to receive general anesthesia.
- Not able to receive angiographic assessment.
- A stenosis > 50% in an extracranial carotid or vertebral artery on the ipsilateral side.

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12615000759594>

- Infarctions due to the perforators occlusion (determined by MRI scan), which is defined as basal ganglia or brainstem/thalamus infarction related with middle cerebral artery or basilar artery stenosis.
 - A high risk (leading to a stroke or death) to deliver the stent to the lesion.
- ... and 11 more (see full listing online)

Locations (1 total)

Fujian, China