

# ACOART Intracranial ISR Pilot: Intracranial DCB in the Treatment of Intracranial In-stent Restenosis

NCT04627870

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Acotec Scientific Co., Ltd
Enrollment	20 participants

## Key Eligibility Criteria

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### Inclusion (8)

- to 80 years of age
  - Confirmed by DSA: in-stent restenosis (ISR) at intracranial segment of internal carotid artery, middle cerebral artery, basilar artery and vertebral artery; ISR is defined as  $\geq 50\%$  stenosis within or immediately adjacent (within 5 mm) of the implanted stent and  $\geq 20\%$  absolute luminal loss
  - presence of ISR associated ischemic stroke or transient ischemic attacks even with medical treatment and strict control of risk factor
  - asymptomatic ISR with severe hypoperfusion in the ISR territories, confirmed by a cerebral blood flow decrease of  $\geq 30\%$  when compared with the perfusion on the contralateral side for anterior circulation lesions or the anterior circulation territory for posterior circulation lesions on CT perfusion, and/or by an American Society of Interventional and Therapeutic Neuroradiology/Society of Interventional Radiology (ASITN/SIR) Collateral Flow Grading System score  $\leq 3$  on DSA.
  - the diameter of target vessel is 2.0-4.5mm
- ... and 3 more (see full listing online)

### Exclusion (22)

- Patients with stroke within 2 weeks before procedure;
  - any history of brain parenchyma or other intracranial subarachnoid, subdural or extradural hemorrhage in the past 30 days.
  - Those who have received thrombolysis within 24 hours before procedure;
  - Deterioration of neurological function within 24 hours before procedure (defined as NIHSS score increased by  $\geq 4$  points over the baseline)
  - patients with thrombus in target vessels.
- ... and 17 more (see full listing online)

## Locations (1 total)

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Beijing Tiantan Hospital, Beijing, China