

Study on the Trans-Carotid Artery Occlusion Shunt System

NCT06924593

Status	RECRUITING
Phase	Not Applicable
Sponsor	Shenzhen Wecan Medical Technology Co.,Ltd
Enrollment	162 participants

Key Eligibility Criteria

Inclusion (12)

- Age \geq 18 years;
- For patients diagnosed with carotid artery stenosis and planned to undergo transcrotid artery endovascular revascularization, one of the following conditions must be met:
 - Symptomatic carotid artery stenosis: The degree of stenosis is determined by non-invasive imaging or angiography to be \geq 50%, and the patient has a history of stroke (mild or non-disabling), transient ischemic attack (TIA), and/or amaurosis fugax within 180 days before the operation.
 - Asymptomatic carotid artery stenosis: The degree of stenosis is determined by non-invasive imaging or angiography to be \geq 70%, and the patient has not experienced any neurological symptoms within 180 days before the operation.
- The modified Rankin Scale (mRs) score \leq 2 before enrollment.

... and 7 more (see full listing online)

Exclusion (21)

- There are extensive atherosclerotic plaques in the proximal part of the common carotid artery on the target lesion side, making the safe operation of the surgery difficult; There are lesions in the access area of the common carotid artery on the target lesion side and its proximal part towards the heart; The distance from the superior border of the clavicle on the target lesion side to the bifurcation of the common carotid artery is less than 5 cm; A stent or graft has been implanted in the carotid artery on the target lesion side; There are acute or subacute thrombosis, arteriovenous malformations at the target lesion or adjacent areas; Severe calcification or tortuosity at the target lesion site makes it difficult to deliver the instruments to the designated location; The target carotid artery is completely occluded;
- Known to have uncontrollable hypertension (systolic blood pressure continuously \geq 180 mmHg or diastolic blood pressure continuously \geq 110 mmHg);
- Combined with symptomatic severe stenosis of other blood vessels (including intracranial and extracranial vessels);
- The patient has experienced an ischemic stroke within 3 months, and the stroke affects the evaluation of the endpoints;
- There has been spontaneous intracranial hemorrhage within 12 months;

... and 16 more (see full listing online)

Locations (1 total)

Beijing Anzhen Hospital, Capital Medical University, Beijing, China

<https://clinicaltrials.gov/study/NCT06924593>

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