

Prospective Trial of IVL for Calcified Carotid Lesions(CREATE Trial)

NCT06936176

Status	RECRUITING
Phase	Not Applicable
Sponsor	Shanghai Bluesail Boyuan Medical Technology Co., Ltd.
Enrollment	204 participants

Key Eligibility Criteria

Inclusion (7)

- Age 18-80 years (inclusive), gender unrestricted.
 - Extracranial carotid artery: Preoperative CT angiography (CTA) confirms symptomatic carotid stenosis e50% or asymptomatic carotid stenosis e70% with calcification (CTA measurement: calcification \gt 50% of circumference).
 - Note: (Extracranial carotid artery: Internal carotid artery or carotid bifurcation; Symptomatic refers to having had a non-disabling ischemic stroke or TIA within 6 months.)
 - Intraoperative digital subtraction angiography (DSA) confirms carotid stenosis e50% (by NASCET criteria) or asymptomatic carotid stenosis e70% (by NASCET criteria).
 - Participants with a pre-enrollment modified Rankin Scale (mRS) score d2.
- ... and 2 more (see full listing online)

Exclusion (21)

- Target lesion caused by non-atherosclerotic disease.
 - Participants with complete occlusion of the target lesion or contralateral carotid artery.
 - Participants with severe disability due to cerebral infarction.
 - Participants with large acute or subacute thrombi near the target lesion, or with arteriovenous malformations or aneurysms.
 - Participants with tortuous target lesion vessels that prevent stent placement.
- ... and 16 more (see full listing online)

Locations (1 total)

Beijing An Zhen Hospital of the Capital University of Medical Sciences, Beijing, China