

Angioplasty with Stent in Symptomatic Intracranial Stenosis Trial-II

Submission date 16/08/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/10/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/10/2007	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2004BA714B-7

Study information

Scientific Title

Acronym
ASSISTII

Study objectives

H0: Adjunctive stenting to optimal medical therapy is not superior to optimal medical therapy alone in reducing ipsilateral stroke risk in patients with symptomatic intracranial atherosclerotic stenoses.

H1: Adjunctive stenting to optimal medical therapy is superior to optimal medical therapy alone in reducing ipsilateral stroke risk in patients with symptomatic intracranial atherosclerotic stenoses.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ischemic stroke

Interventions

Stent-assisted angioplasty of the offending intracranial stenosis plus optimal medical therapy versus optimal medical therapy alone

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Ipsilateral stroke, fatal or non-fatal, within 12 months
2. Events of clinically-driven emergency revascularization related to the treated stenosis
3. Modified Rankin score in 12 months

Key secondary outcome(s)

1. Stroke and death unrelated to the target stenosis
2. Acute myocardial infarction in 12 months
3. Follow up cerebral angiography or magnetic resonance (MR) angiography, CT and CT-perfusion in 6 months
4. NIHSS in 12 months

Completion date

30/09/2009

Eligibility

Key inclusion criteria

1. 18-75 years of age
2. ≥ 1 major atherosclerotic risk factors (arterial hypertension, hyperlipidemia, diabetes mellitus, hyperhomocystinemia and smoking)
3. Recurrent ischemic events (transient ischemic attack [TIA] and/or stroke) attributed to an intracranial stenosis $\geq 50\%$ at digital subtraction angiography (DSA)
4. Evidence of perfusion deficit at the territory referable to the target stenosis in computed tomography (CT)-perfusion
5. The diameters of the parent arteries were between 2.0 to 4.0 mm, and length of stenoses < 12 mm
6. Modified Rankin score ≤ 2 prior to last ischemic event

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

1. Stenosis of non-atherosclerotic origin (for example, vasculitis, Moya Moya disease and fibromuscular dysplasia)
2. Intracranial hemorrhage and major ischemic stroke (National Institutes of Health-Stroke-Scale [NIHSS] ≥ 8) in the same hemisphere as the target lesion within 6 weeks
3. A potential source of cardiac embolism
4. Concurrent intracranial tumors, cerebral arteriovenous malformation (AVM) and aneurysms
5. Presence of a neurological illness that can confound the diagnosis of TIA or stroke
6. Known contraindication to aspirin, clopidogrel, probucol, heparin, stainless steel, anesthesia, or X-ray contrast
7. Uncorrectable bleeding diathesis; previous stenting of the target artery
8. A positive pregnancy test
9. Life expectancy < 1 year because of other medical conditions
10. Patients were not eligible if they could not cooperate with the study procedures or provide informed consent

Date of first enrolment

01/09/2005

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

China

Study participating centre

No. 6 Tiantan Xili

Beijing

China

100050

Sponsor information

Organisation

The Ministry of Health of the People's Republic of China

ROR

<https://ror.org/01mv9t934>

Funder(s)

Funder type

Government

Funder Name

The Ministry of Health of The People's Republic of China

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes