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Angioplasty with Stent in Symptomatic Intracranial Stenosis Trial-II

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.strokecn.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/09/2005

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 ≥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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
399

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
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100050

Sponsor information

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

Sponsor details
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Sponsor type
Government

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration