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

Study website http://www.strokecn.com

Contact information

Type(s) Scientific

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Contact details

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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

 Stroke and death unrelated to the target stenosis
 Acute myocardial infarction in 12 months
 Follow up cerebral angiography or magnetic resonance (MR) angiography, CT and CTperfusion in 6 months
 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

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 China 100050

Sponsor information

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

Sponsor details No.1 The South Road Of Xizhimenwai Beijing China 100044 manluzhu@yahoo.com.cn

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