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Endovascular versus drug therapy to symptomatic middle cerebral artery (MCA) stenosis

Submission date	Recruitment status	[_] Prospectively registered
01/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2019	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Ling Feng

Contact details
Department of Neurosurgery
Xuanwu Hospital of Capital Medical University
Changchun Road
Xuanwu District
Beijing
China
100053
-
ling-feng@vip.163.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial of Symptomatic Middle cerebral artery (MCA) stenosis: Endovascular versus Drug therapy

Acronym
RaSMED

Study objectives
Intracranial arteriostenosis is one of the main causes of stroke. Although anti-platelet and anti-coagulation therapy are widely applied nowadays, the effectiveness of such methods is still controversial. Each treatment method has its advantages and disadvantages. There is evidence that anti-coagulation and anti-platelet therapies are not effective to all patients.

Endovascular therapy has been applied for several years, including stent technology and dilation with balloon, which has only been proven to be effective by a single-centre trial with a small size. Designing a randomised controlled trial is necessary to supply evidence to prove the effectiveness of endovascular therapy, which can also supply evidence for standardising the therapy of intracranial stenosis. Our study hypothesises that endovascular method is not inferior to medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Xuanwu Hospital Ethics Board gave approval on the 19th March 2008 (ref: XW-EA-08008)

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Intracranial atherosclerotic stenosis

Interventions
Drug therapy:
Clopidogrel 75 mg and aspirin 100 mg every day (QD), maintaining such a plan for 3 months. After that, aspirin 100 mg or clopidogrel 75 mg should be retained.

Endovascular therapy:
In this group, all the patients should take dual-antiplatelet drugs 3 - 5 days before treatment (clopidogrel 75 mg and aspirin 100 mg, every day). General anaesthesia will be selected, all the patients will receive stent-planting therapy. After the endovascular therapy, the anti-platelet drugs will be continued for 3 months. And then, one of the anti-platelet drugs will be maintained for the rest of life. Anticoagulation therapy will be applied for only 3 days after the stent-planting.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The patient died or experienced stroke within 30 days after the beginning of treatment
2. The stent does not cover the lesion or stenosis can't be retrieved completely (less than 50%)

Secondary outcome measures
DSA should be performed after six months if the patient receives endovascular therapy or the patient experiences stroke which is related to the target vessel.

Overall study start date
01/01/2008

Completion date
01/03/2009

Eligibility

Key inclusion criteria
1. Aged 25 - 75 years old (both genders) - half/bilateral stenosis on the M1 segment of the MCA - which is related to the onset of the cerebral ischaemia
2. Digital subtraction angiography (DSA) should be performed to verify such points as follows:
2.1. The degree of vascular stenosis should be greater than or equal to 70%
2.2. The length of lesion should be within 10 mm
2.3. The diameter of distal vessel should be more than 2 mm
3. Asymptomatic vascular stenosis greater than or equal to 50%
4. Atherosclerotic stenosis
5. National Institutes of Health Stroke Score (NIHSS) less than 15, and modified Rankin Scale

(mRS) less than or equal to 3
6. The patient should be tolerant to both of the anti-platelet drugs
7. The patient should not be pregnant

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
166

Total final enrolment
70

Key exclusion criteria
1. Acute cerebral stroke occurs in the past one week, which is correlated to the vascular lesion
2. Those patients who have diseases of a haemorrhagic tendency
3. Anticipation of life span is within one year, especially in those patients who have a combined malignant disease
4. Acute dissecting aneurysm; vascular lesion is due to vasculitis, moya-moya disease, vasculopathy because of radiation, muscle fibrodysplasia
5. Calcification can be observed in the lesion segment, which is difficult to be dilated. Thrombus can be seen in the lumen of blood vessel.
6. Intracranial haematoma, tumour, brain arteriovenous malformation (BAVM), intracranial aneurysm (AM) (not including an AM whose diameter is less than 5 mm, and that is located in a different circle region)
7. Patients are excluded:
7.1. When there is a contraindication to heparin
7.2. When they are not tolerant to x-rays or anaesthesia
7.3. When their haemoglobin is less than 10 g/dL or their platelet is less than 100000/l
8. Patients who received thrombolysis in the past 24 hours
9. Symptomatic coronary artery disease, where revascularisation is needed
10. Surgical intervention has been performed in the last one month or will be performed in the next three months
11. Endovascular therapy was performed in the same target vessel previously
12. Multi-stenosis are found in the same target vessel, the degree of which is more than 50%
13. Stent-planting is hard to be performed because of the circuitry of the vessels
14. Symptomatic intracranial arterial stenosis is found not only in one vessel

Date of first enrolment
01/01/2008

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
China

Study participating centre
Department of Neurosurgery
Beijing
China
100053

Sponsor information

Organisation
Beijing Municipal Science and Technology Commission (China)

Sponsor details
Xizhimen South Road 16#
Beijing
China
100053
+86 (0)10 6615 3395
bjkwwz@sina.com

Sponsor type
Government

Website
http://www.bjkw.gov.cn/n1143/index.html

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and Technology Commission (China) - Beijing Scientific Project (ref: D0905004040131)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2012	04/07/2019	Yes	No