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Imaging-based Thrombolysis trial in Acute Ischemic Stroke -III

Submission date	Recruitment status	[ ] Prospectively registered
14/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/10/2007	Circulatory System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5

Study information

Scientific Title

Acronym
ITAIS- III

Study objectives
Whether the patients without occlusion or significant stenosis of the large vessels should receive thrombolysis had been focused on and questioned for a long time. However, there is still no large Randomised Controlled Trial (RCT) to prove if these patients can benefit from thrombolysis. The objective of this trail is to investigate:
1. For the selected acute ischemic stroke patients without large vessels occlusion or significant stenosis, whether the IntraVenous (IV) thrombolysis can improve the clinical outcome if the mismatch exists on CTP/Computed Tomography Angiography-Source Images (CTA-SI) scan in 3-9 hr time-window
2. For the selected acute ischemic stroke patients without large vessels occlusion or significant stenosis, whether the IV thrombolysis can improve the blood perfusion of brain if the mismatch exists on CT perfusion (CTP)/CTA-SI scan in 3-9 hr time-window
3. For the selected acute ischemic stroke patients without large vessels occlusion or significant stenosis, but the mismatch exists on CTP/CTA-SI scan in 3-9 hr time-window, whether the safety of IV thrombolysis is better than the NINDS trial which was in 3 hr window or implemented on the patients with large vessels occlusion or significant stenosis in 3-9 hr time-window.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval gained from the Beijing Tiantan Hospital Capital Medical University Ethics Board on October 10, 2006.

Study design
A prospective, multi-center, assessor-blind controlled trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute ischemic stroke

Interventions
Patients included were divided into recombinant tissue Plasminogen Activator (rt-PA) (0.9 mg /kg) intravenous thrombolysis group and regular treatment group according to the intention of doctors and patients.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Recombinant tissue Plasminogen Activator (rt-PA)

Primary outcome measure
Proportion of participants who achieve the following:
1. Reperfusion improvement, assessed 24 to 48 hours post-treatment and defined as either greater than or equal to 30% reduction of Mean Transit Time (MTT) volume of abnormality
2. Good clinical outcome at 90 days defined as a modified Rankin score (mRS) of 0-1
3. Intracerebral haemorrhage within 24-36 h after thrombolysis

Secondary outcome measures
Proportion of participants who achieve the following:
1. mRS 0 to 2 at 90 days
2. Barthel Index (BI) score 75 to 100 at 90 days
3. NIHSS 4 points improvement or 0-1 at 2 hours after treatment
4. NIHSS 4 points improvement or 0-1 at 24 to 48 hours
5. NIHSS 4 points improvement or 0-1 at day 7

Overall study start date
01/10/2007

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Female or male inpatients
2. Age 18-80 years
3. Clinical diagnosis of ischaemic stroke
4. Onset of symptoms within 3-9 hours prior to initiation of thrombolysis treatment
5. Stroke symptoms present for at least 30 minutes and has not significantly improved before treatment
6. The National Institutes of Health Stroke Scale (NIHSS) score greater than or equal to 4
7. m-CT screening to be started within 8.5 hrs after stroke onset
8. Perfusion abnormality of CT scan >2cm in diameter involving hemisphere
9. CT Perfusion/CTA source image mismatch greater than or equal to 20%

10. CTA shows occlusion or significant stenosis of large vessels (Thrombolysis In Cerebral Ischemia [TICI] grade is 0 or 1)
11. Patients are willing to receive thrombolysis treatment and to give informed consent
12. Patients are willing and able to comply with the study protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Evidence of IntraCranial Haemorrhage (ICH), brain tumors, vascular malformation, aneurysm, SubArachnoid Hemorrhage (SAH)
2. Major infarct involving greater than 1/3 of Middle Cerebral Artery (MCA) territory on the CTA-SI
3. Presenting obvious neurologic deficits because of past stroke (mRS >2)
4. Severe stroke as assessed clinically (e.g. The National Institute of Health Stroke Scale [NIHSS] >25) and/or by appropriate magnetic imaging techniques.
5. Seizure at onset of stroke
6. Prior stroke within the last 3 months
7. Patients with any history of prior stroke and concomitant diabetes
8. Administration of heparin within the previous 48 hours and a thromboplastin time exceeding the upper limit of normal for laboratory
9. Platelet count of below 100,000/mm3
10. Uncompensated hypertension at study entry or hypertension requiring aggressive treatment to reduce blood pressure to nonhypertensive limits. Uncompensated hypertension is defined as systolic blood pressure >185 mm Hg or diastolic blood pressure >=110 mm Hg on 3 repeated measures at least 10 minutes apart
11. Blood glucose <50 or >400 mg/dl
12. Known haemorrhagic diathesis within the last 6 months
13. Patients receiving oral anticoagulants e.g. warfarin sodium, and coagulant response time (INR) >1.5
14. Known history of or suspected intracranial haemorrhage including subarachnoid haemorrhage
15. Pregnancy or lactation
16. Any history of severe central nervous system damage (i.e. neoplasm, aneurysm, intracranial or spinal surgery)
17. Haemorrhagic retinopathy,e.g. in diabetes (vision disturbances may indicate haemorrhagic

retinopathy)
18. Bacterial endocarditis, pericarditis
19. Prolonged traumatic external heart massage, or recent (less than 10 days) obstetrical delivery or recent puncture of a non-compressible blood-vessel (e.g. subclavian or jugular vein puncture)
20. Acute pancreatitis
21. Documented ulcerative gastrointestinal disease during the last 3 months,
22. Oesophageal varices, arterial aneurysm, arterial/venous malformation
23. Neoplasm with increased bleeding risk
24. Severe liver disease including hepatic failure, cirrhosis, portal hypertension, oesophageal varices and active hepatitis
25. Major surgery or significant trauma in past 10 days
26. Known serious sensitivity to alteplase

Date of first enrolment
01/10/2007

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
China

Study participating centre
Neurology Department
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100050

Sponsor information

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Sponsor type

Hospital/treatment centre

Website
http://www.bjtth.com/

ROR
https://ror.org/003regz62

Funder(s)

Funder type
Government

Funder Name
The Ministry of Science and Technology and the Ministry of Health of the People's Republic of China - the key scientific research program of the 11th National Five-Year Planning 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