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Thrombolysis Register of Acute Ischaemic Stroke in China

Submission date	Recruitment status	[ ] Prospectively registered
03/08/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/08/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2021	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
Thrombolysis Register of Acute Ischaemic Stroke in China

Acronym
TRAIS-CHINA

Study objectives
1. To evaluate the clinical status of recombinant tissue Plasminogen Activator (rt-PA) thrombolysis in acute ischaemic stroke (within a three-hour time-window) in China
2. To assess whether the safety and efficacy of thrombolysis in acute ischaemic stroke are equivalent in the settings of randomised controlled trials and during implementation into clinical routine in China

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
An open, prospective, multicentre, non-randomised observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute ischaemic stroke

Interventions
All patients will be given intravenous (i.v.) rt-PA 0.9 mg/kg body weight (bw), 10% bolus, one-hour infusion, as part of their treatment. Patients will then be observed and followed-up for three months.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. Symptomatic intracerebral haemorrhage within 24 to 36 hours
2. Death (modified Rankin Scale [mRS] = 6) within three months

Secondary outcome measures
Independence for the activities of daily living at three months defined as a modified Rankin score (mRS) of 0 to 2.

Overall study start date
01/04/2007

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Female or male inpatients
2. Age 18 to 80 years
3. Clinical diagnosis of ischaemic stroke
4. Onset of symptoms within three hours prior to initiation of thrombolysis treatment
5. Stroke symptoms present for at least 30 minutes and has not significantly improved before treatment
6. Patients are willing to receive thrombolysis treatment and to give informed consent
7. Patients are willing and able to comply with the study protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
330

Key exclusion criteria
1. Evidence of Intracranial Haemorrhage (ICH), brain tumours, vascular malformation, aneurysm, Subarachnoid Haemorrhage (SAH) or major early infarct signs involving greater than 1/3 of

Middle Cerebral Artery (MCA) territory on the Computed Tomography (CT)-scan
2. Severe stroke as assessed clinically (e.g. National Institutes of Health Stroke Scale [NIHSS] greater than 25) and/or by appropriate imaging techniques
3. Seizure at onset of stroke
4. Prior stroke within the last three months
5. Patients with any history of prior stroke and concomitant diabetes
6. Administration of heparin within the previous 48 hours and a thromboplastin time exceeding the upper limit of normal for laboratory
7. Platelet count of below 100,000/mm^3
8. 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 greater than 185 mmHg or diastolic blood pressure greater than or equal to 110 mmHg on three repeated measures at least 10 minutes apart
9. Blood glucose less than 50 or greater than 400 mg/dl
10. Known haemorrhagic diathesis within the last six months
11. Patients receiving oral anticoagulants, e.g., warfarin sodium, and International Normalised Ratio (INR) greater than 1.5
12. Known history of or suspected intracranial haemorrhage including subarachnoid haemorrhage
13. Pregnancy or lactation
14. Any history of severe central nervous system damage (i.e., neoplasm, aneurysm, intracranial or spinal surgery)
15. Haemorrhagic retinopathy, e.g., in diabetes (vision disturbances may indicate haemorrhagic retinopathy)
16. Bacterial endocarditis, pericarditis
17. 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)
18. Acute pancreatitis
19. Documented ulcerative gastrointestinal disease during the last three months
20. Oesophageal varices, arterial-aneurysm, arterial/venous malformation
21. Neoplasm with increased bleeding risk
22. Severe liver disease, including hepatic failure, cirrhosis, portal hypertension oesophageal varices) and active hepatitis
23. Major surgery or significant trauma in past 10 days
24. Known serious sensitivity to Alteplase

Date of first enrolment
01/04/2007

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
China

Study participating centre

Beijing Tiantan Hospital
Beijing
China
100050

Sponsor information

Organisation
Beijing Tiantan Hospital (China)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/003regz62

Funder(s)

Funder type
Government

Funder Name
The Key Scientific Research Program of the 11th National Five-Year Planning of China (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration