Effectiveness and safety of IV rt-PA treatment in Chinese AIS patients aged above 80 years: a real-world study (0135-0349)

First published: 11/06/2021

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Study Planned

Administrative details

EU PAS number

EUPAS41540

Study ID

48055

DARWIN EU® study

No

Study countries

☐ China

Study description

Alteplase treatment in elderly AIS patients

Study status

Planned

Research institutions and networks

Institutions

Zhejiang University

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Institution

The Second Affiliated Hospital,School of Medicine

Contact details

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Primary lead investigator

Min Lou

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/08/2021

Actual: 18/08/2021

Study start date
Planned: 01/12/2022

Date of final study report
Planned: 30/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Int’l Trading (Shanghai) Co., Ltd

Regulatory

Was the study required by a regulatory body?

Unknown

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

• To compare the 1-year neurological functional outcome (as measured by modified Rankin Scale mRS score) of Chinese AIS patients aged > 80 years receiving IV rt-PA treatment within 4.5 hours of symptom onset versus those who arrived or were admitted to the hospital within 4.5 hours of symptom onset and did not receive reperfusion therapy.

Population studied

Age groups

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

1301

Study design details

Outcomes

• To compare the 1-year neurological functional outcome (as measured by modified Rankin Scale mRS score) of Chinese AIS patients aged > 80 years receiving IV rt-PA treatment within 4.5 hours of symptom onset versus those who arrived or were admitted to the hospital within 4.5 hours of symptom onset and did not receive reperfusion therapy. • Any intracranial haemorrhage (ICH) during hospitalisation • All-cause mortality during hospitalisation • Independence (mRS 0-2) at 1 year • Distribution of mRS score at 1 year • All-cause mortality at 1 year • Baseline characteristics (age, gender, NIHSS, etc.)

Data analysis plan

To account for potential confounding, the study cohorts (patients who received IV rt-PA and patients who did not receive reperfusion treatment) will be matched by baseline characteristics using the propensity score matching (PSM) method. The PSM aims to balance the 2 treatment cohorts on baseline covariates. The feasibility of PSM will be evaluated based on available sample size and descriptive results. If patient characteristic between the 2 cohorts are significantly different, the study design will be re-evaluated before proceeding to analysis. The Nearest Neighbour method of PSM will be used to select the matched samples. The final list of baseline characteristics in the PSM will be decided in conjunction with Boehringer Ingelheim. All the variables listed in the covariates will be considered. The distribution of baseline characteristics will be presented before and after the matching process.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No