Characteristics and in-hospital outcomes of Chinese elderly (>80 years) patients with acute ischemic stroke receiving intravenous recombinant tissue plasminogen activator treatment within 4.5 hours of symptom onset (0135-0348)

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Study | Planned

Administrative details

EU PAS number

EUPAS41509

Study ID

48061

DARWIN EU® study

No

Study countries

China

Study description

Alteplase in elderly AIS during hospitalization

Study status

Planned

Research institutions and networks

Institutions

Beijing Tiantan Hospital

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Institution

Contact details

Study institution contact

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Primary lead investigator

Yongjun Wang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/09/2021

Actual: 08/10/2021

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

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 describe the in-hospital clinical outcomes of AIS patients who were treated with IV rt-PA within 4.5 hours of symptom onset, among those aged 18 to 80 years and >80 years, respectively.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Database analysis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

62800

Study design details

Outcomes

describe the characteristics of AIS patients who arrived or were admitted to the hospital within 4.5 hours of symptom onset and were treated with or without IV rt-PA among different age groups describe the percentage of patients receiving IV rt-PA treatment within 4.5 hours of symptom onset among AIS patients aged 18 to 80 years and above 80 years

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Data analysis plan

The primary and secondary outcome will be analysed by using descriptive statistics for group 1 and group 2. The baseline characteristics (covariates) will be analysed by using descriptive statistics for all 4 groups in this study, where group 1 is compared against group 2 and group 1 is compared against group 3. For general statistical considerations, the descriptive statistics for continuous variables will include mean, standard deviation, 95% CI of mean, median, interquartile range, for categorical variables, counts, percentages and 95% CI will be included. For categorical variables, 95% Clopper-Pearson confidence interval will be used.

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.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Prospective patient-based data collection

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