

Temporal trends of thrombolysis treatment in Chinese acute ischemic stroke (AIS) patients from 2007 2017: analysis of China National Stroke Registry (CNSR) phase I, II, and III

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Study

Planned

Administrative details

EU PAS number

EUPAS33973

Study ID

33974

DARWIN EU® study

No

Study countries

 China

Study description

Primary objectives: • To investigate the temporal changes in the proportion of intravenous recombinant plasminogen activator (IV rtPA) treatment from 2007 to 2017 among intravenous thrombolytics (IVT) eligible patients and overall AIS patients in China, • To investigate the temporal changes in IV rtPA treatment time intervals from 2007 to 2017 among IV rtPA treated patients in China. Secondary objectives: • To describe the demographic and clinical characteristics of the IV rtPA treated patients, IVT eligible patients and the overall AIS patients from the CNSR phase I to phase III.

Study status

Planned

Research institutions and networks

Institutions

Beijing Tiantan Hospital

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Institution

Contact details

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Primary lead investigator

Yongjun Wang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2020

Study start date

Planned: 15/05/2020

Date of final study report

Planned: 01/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

No

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Main study objective:

In order to understand the impact of these efforts on the clinical practices for AIS treatment in China, we plan to evaluate the 10 year temporal changes from 2007 2017, in the IV rtPA treatment proportion and treatment time intervals of AIS patients by using the CNSR phase I, II, and III. In addition, the demographic and clinical characteristics of the AIS patients will be described.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Ischaemic stroke

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

50000

Study design details

Outcomes

- To investigate the temporal changes in the proportion of intravenous recombinant plasminogen activator (IV rtPA) treatment from 2007 to 2017 among intravenous thrombolytics (IVT) eligible patients and overall AIS patients in China,
- To investigate the temporal changes in IV rtPA treatment time

intervals from 2007 to 2017 among IV rtPA treated patients in China. • To describe the demographic and clinical characteristics of the IV rtPA treated patients, IVT eligible patients and the overall AIS patients from the CNSR phase I to phase III

Data analysis plan

The study is descriptive in nature. For continuous data, descriptive statistics (number of patients, mean, standard deviation SD, minimum, median, interquartile range, and maximum) will be presented. Categorical data will be presented as frequency and proportion with 95% CI as appropriate. Selected outcomes will be analyzed with data from hospitals participated across all phases of CNSR. These outcomes will also be standardized by hospital (based on phase III).

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)

[Disease registry](#)

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