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

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Study Finalised

Administrative details

EU PAS number

EUPAS33970

Study ID

34431

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 I to III.

Study status

Finalised

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

Actual: 21/09/2020

Data analysis start date

Planned: 29/05/2020

Date of final study report

Planned: 01/07/2020

Actual: 10/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

0135-0343_CTP_final-rule_Redacted.pdf (366.75 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

0135-0343

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

This is a non interventional study based on existing data from the CNSR.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ACTILYSE

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

50.000

Study design details

Outcomes

For all the three waves of CNSR, the following primary outcomes will be assessed: Proportion of patients who received IV rtPA treatment within 3h of symptom onset (patient group C) among 2hr IVT eligible patients (patient group B), Proportion of patients who received IV rtPA treatment within 4.5h of symptom onset (patient group C') among 3.5h IVT eligible patients (patient group B'). Among all AIS patients: Proportion of patients who arrived at hospital within 2h of symptom onset and who received IV rtPA treatment within 3h of symptom onset Proportion of patients who arrived at hospital within 3.5h of symptom onset and who received IV rtPA treatment within 4.5h of symptom onsetFor other secondary outcomes, please refer to protocol.

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 analyze with data from hospital participated across all phases

of CNSR. These outcomes will also be standardized by hospital (based on phase III).

Documents

Study results

0135-0343_Synopsis.pdf (430.03 KB)

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