1-year clinical outcomes after intravenous rt-PA for Chinese AIS patients (0135-0350)

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Study Finalised

Administrative details

EU PAS number

EUPAS41543

Study ID

50341

DARWIN EU® study

No

Study countries

China

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Min Lou

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2021

Actual: 01/12/2021

Study start date

Planned: 01/06/2022

Actual: 01/04/2022

Date of final study report

Planned: 30/12/2023

Actual: 20/02/2023

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 topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

• All-cause mortality at 1 year (mRS=6)

Study drug and medical condition

Additional medical condition(s)

Acute Ischaemic Stroke

Population studied

Short description of the study population

Patients with acute ischaemic stroke

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)

Special population of interest

Other

Special population of interest, other

Patients with acute ischaemic stroke

Estimated number of subjects

11700

Study design details

Outcomes

• All-cause mortality at 1 year (mRS=6), • Functional independence (mRS 0-2) at 1 year • Favourable clinical outcome (mRS 0-1) at 1 year • mRS 5-6 at 1 year • Distribution of mRS score at 1 year

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 characteristics 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.

Data sources

Data sources (types)

Other

Data sources (types), other

ZSQCC platform

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