Safe Implementation of Treatments in Stroke (SITS) - Intravenous thrombolysis in acute ischaemic stroke patients over 80 years, SITS-IVT>80 years study (SITS ELDERLY)

First published: 08/02/2020

Last updated: 14/03/2024

Study | Planned

Administrative details

EU PAS number

EUPAS33011

Study ID

33012

DARWIN EU® study

No

Study countries

Austria

Belgium

Cyprus
Denmark
Finland
France
Germany
Greece
Iceland
Ireland
Italy
Luxembourg
Malta
Netherlands
Norway
Portugal
Spain
Sweden
United Kingdom

Study description

The SITS-IVT>80 years is a retrospective study based on datacollected in the SITS-ISTR setting from acute ischemic strokepatients > 80 years of age. The study aims to evaluate theincidence rate with 95% CI of SICH, death and functionalindependence/favourable outcome within 90 days for ischaemicstroke patients treated with rt-PA in clinical routine settings. Inthe proposed SITS-IVT>80 years study using the SITS registrywe plan to identify approximately 1000 patients older than 80years treated with IV Alteplase otherwise fulfilling SmPCcriteria in the post-approval period of 3 years (from 1 July 2018to 30 June 2021) and also to identify 1000 patients older than 80years treated with IV Alteplase otherwise fulfilling SmPCcriteria in the pre-approval period of 3 years (from June 2015 toJune 2018). In both periods, at least 500 patients should

beregistered from centres of European countries being part of themutual recognition.The objective of the SITS-IVT>80 years is to compare the safetyand other outcome parameters between the post-approval >80years and pre-approval >80 years AIS patients using the dataalready collected in SITS-ISTR.

Study status

Planned

Research institutions and networks

Institutions

Karolinska University Hospital

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Institution

Networks

Safe Implementation of Treatments in Stroke (SITS)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Niaz AHMED

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/01/2020

Study start date
Planned: 17/02/2020

Date of final study report
Planned: 01/06/2022

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

Other study registration identification numbers and links

Boehringer Ingelheim Study Number 0135-0344

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

Compare safety and efficacy of the use of IV rtPA in patients above 80 years of age, before the EU approval, and after.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Actilyse

Medical condition to be studied

Ischaemic stroke

Population studied

Age groups

- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

2000

Study design details

Outcomes

 Safety: SICH per SITS-MOST definition Mortality (mRS=6) within 90 days

Outcome: Functional Independency as defined by mRS 0-2 within 90 days,

Patient characteristics at baseline including stroke severity (NIHSS)

Outcomes: - Favourable outcome as defined by mRS 0-1 within 90 days -

Secondary safety: SICH per ECASS 2 within 90 days - Delays of Management: Time from onset of symptoms – start of Treatment // Time from onset of symptoms – door (or as captured in the registry arrival at hospital) // Door – needle time

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Data analysis plan

A non-interventional post-approval study on SITS-ISTR existing data of intravenous rt-PA (0.9 mg/kg) in acute ischaemic stroke patients over 80 years, according to the Summary of Product Characteristics (SmPC) of European countries being part of the mutual recognition procedure within the academic SITS-ISTR (International Stroke Thrombolysis Registry, ongoing since December 2002).Descriptive statistics (absolute and relative frequencies, means, standard deviations, medians, inter quartile ranges, minimum and maximum values, 95% confidence intervals and proportions, as appropriate) for baseline and demographic characteristics for all included patients will be provided. To compare demographic and clinical baseline characteristics between pre-approval and post-approval patients over >80years, standardized differences will be used. Multivariable analyses (exploratory) with adjustment for differences or imbalances in prognostic variables for outcome comparison will be performed.

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

Prospective patient-based data collection, Retrospective and 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