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

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# Administrative details

U PAS number	
UPAS33011	
tudy ID	
3012	
ARWIN EU® study	
0	
tudy countries	
Austria	
Belgium	

Сур	/prus	
Der	enmark	
Finl	nland	
Fra	ance	
Ger	ermany	
Gre	reece	
Icel	eland	
Irel	eland	
Ital	aly	
Lux	ixembourg	
Mal	alta	
☐ Net	etherlands	
☐ Nor	orway	
Por	ortugal	
Spa	pain	
Swe	veden	
Uni	nited 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 >80 years and preapproval >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

### Niaz AHMED niaz.ahmed@sll.se

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

#### 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 preapproval and post-approval patients over >80 years, 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**