Pradaxa Initiation Post-Stroke Study: SITS-Pradaxa 1. A retrospective analysis from the SITS-AF Registry on treatment initiation of dabigatran etexilate in non-valvular atrial fibrillation patients hospitalized with acute ischemic stroke

First published: 18/07/2017

Last updated: 30/06/2020

Study Finalised

Administrative details

EU PAS number

EUPAS17165

Study ID

36112

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Italy
- [ ] Lithuania
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Ukraine
- [ ] United Kingdom

Study description

This is an observational study in patients with non-valvular atrial fibrillation (NVAF) presenting to the hospital with a first acute ischemic stroke based on existing data recorded in the SITS International Registry (located in Sweden) by physicians in several European countries. The aim of this study is to explore the

current real world use of dabigatran for stroke prevention in NVAF patients in the post-stroke setting. Data from eligible European patients registered in the SITS Registry will be considered, countries of origin are not known a priori.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

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Institution

Networks

SITS International Network

Contact details

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Study contact

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Primary lead investigator

Christine Teutsch

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/08/2015

Actual: 18/12/2015

Study start date

Planned: 21/07/2017

Actual: 15/11/2018

Data analysis start date

Planned: 11/02/2019

Date of final study report

Planned: 30/04/2019

Actual: 11/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

SITS-Pradaxa 1_protocol_redacted.pdf(902.4 KB)

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the timing of dabigatran treatment initiation in patients with non-valvular atrial fibrillation (NVAF) after hospitalization for first ever ischaemic stroke (the index event) in order to prevent secondary stroke

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Ischaemic stroke

Population studied

Short description of the study population

Patients with non-valvular atrial fibrillation (NVAF) presenting with their first ever acute ischemic stroke who are registered in the SITS International Registry from 1 July 2014 until approximately 31 July 2018 will be included in the study.

Inclusion criteria

1. Patients with non-valvular Atrial Fibrillation (NVAF)
2. Patients presenting with their first acute ischemic stroke
3. ≥ 18 years of age

Exclusion criteria

1. Documentation that the patient was enrolled or is planned to be enrolled in an investigational clinical trial at the time of the onset of the index event and for the
duration of the data collection

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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

1000

Study design details

Outcomes

The time lapsed from the index event to the initiation of the dabigatran treatment. This will be further categorized in specified time periods.The following time periods will be considered, but could be revised (e.g. merging categories) depending on sample size 0-24h, >24-72h, >3-7d >7-14d, >14-28d, >28d-3m. Description of baseline characteristics for patients treated with dabigatran according to time of dabigatran initiation.Description of self-reported factors important for physician’s decision when to initiate dabigatran and which dabigatran dose is used in the post-ischemic stroke setting for secondary prevention of stroke and safety in NVAF.

Data analysis plan

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. For the baseline characteristics the percentage proportions will be calculated by dividing the number of events by the total number of patients, excluding missing or unknown cases, as was generally done in previous publications (e.g. SITS-MOST and / or SITS-ISTR).The main analysis will focus on NVAF patients presenting with first ischemic acute stroke and treated with dabigatran within 3 months of index event.For patients initiated on dabigatran within 3 months of

index event, the time to dabigatran treatment initiation will be summarized as a continuous variable as well as categorical.

Documents

Study results

SITS-Pradaxa1_report synopsis_11-Jan-2020.pdf(446.97 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