Prospective Record Of the use of Dabigatran in patients with Acute Stroke or TIA (PRODAST)

First published: 02/07/2015

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Study | Finalised

Administrative details

EU PAS number

EUPAS8525

Study ID

26744

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The multi-center, prospective PRODAST study is investigating patients with TIA or ischemic stroke and non-valvular AF both with and without previous oral anticoagulation. It consists of a baseline visit and a 3 months central follow-up for patients who were discharged with dabigatran, vitamin K-antagonists, antiplatelets only, or no oral antithrombotic treatment at all. Thus, data on the use of dabigatran and vitamin K-antagonists in routine clinical practice will be collected to describe how dabigatran is prescribed and used in the population of AF patients with recent cerebrovascular events and how these factors influence important outcome and safety events. The utilization of dabigatran will be assessed with regards to treatment persistence, compliance, proportion of patients discontinuing treatment and reason for discontinuation as well clinical endpoints such as major bleeding, stroke or systemic embolism. Due to the fact that patients will be treated according to local medical practice it is possible that medication will be changed during the observation period. In the follow-up, the study will use data from the first as well as from the second prescribed medication. To explore a long-term effect of anticoagulation, survival up to one year will be assessed.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Hans Diener

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/12/2014

Study start date

Actual: 02/07/2015

Data analysis start date

Planned: 27/04/2022

Actual: 27/04/2022

Date of final study report

Actual: 15/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharma GmbH

Study protocol

PRODAST_Beobachtungsplan_V3 8_20150609_Unterschr_geschwärzt.pdf (1.62 MB)

PRODAST_Beobachtungsplan_V5.0_20180924_geschwärzt.pdf (1.77 MB)

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

ClinicalTrials.gov Identifier: NCT02507856

https://clinicaltrials.gov/ct2/show/NCT02507856?titles=prodast&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

- if 3-month major bleeding event rate following TIA or ischemic stroke in patients with AF is not significantly increased with dabigatran administered early compared to dabigatran treatment started after 7 days or VKA started at any time - occurrences of major bleeding over time and optimal time point for dabigatran administration - recurrent stroke rates under treatment (dabigatran, VKA etc.)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, multi-center observational study

Study drug and medical condition

Medicinal product name

PRADAXA

Anatomical Therapeutic Chemical (ATC) code

(B01AA) Vitamin K antagonists

Vitamin K antagonists

(B01AB) Heparin group

Heparin group

(B01AC) Platelet aggregation inhibitors excl. heparin

Platelet aggregation inhibitors excl. heparin

(B01AE) Direct thrombin inhibitors

Direct thrombin inhibitors

(B01AF) Direct factor Xa inhibitors

Direct factor Xa inhibitors

Medical condition to be studied

Ischaemic stroke

Transient ischaemic attack

Atrial fibrillation

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with recent (≤ 1 week from index) ischemic stroke or transient ischaemic attack (TIA) and with confirmed non-valvular atrial fibrillation (AF) receiving treatment with dabigatran, vitamin K antagonists (VKAs), antiplatelets only or no oral antithrombotic treatment identified from July 2015 to November 2020.

Inclusion criteria:

1. Age ≥18 years at enrollment
2. Male or female patient willing and able to provide written informed consent for data transmission. For patients who are not legally competent to sign this informed consent for data transmission exceptions/special cases.
3. Patient with ischemic stroke or TIA within the last 7 days.
4. Patient diagnosed with non-valvular AF. Documentation of AF by 12 lead ECG, ECG rhythm strip, monitor print-out, pacemaker/ICD electrocardiogram, Holter ECG (duration of AF episode at least 30 seconds) or written physician´s diagnosis prior to index event needed for all enrolled patients.
5. Patients treated with either dabigatran, VKA, antiplatelets only or no oral antithrombotic treatment at all.

Exclusion criteria:
1. Presence of any mechanical heart valve, or valve disease that is expected to require valve replacement intervention (surgical or non-surgical) during the next 3 months.
2. Current participation in any randomized clinical trial of an experimental drug or device.
3. Women of childbearing age without anamnestic exclusion of pregnancy or not using an effective contraception or nursing mothers.
4. In case, it will be determined at baseline or at discharge that patients have been treated in deviation from the effective summary of product characteristics (SmPC) for dabigatran (Pradaxa), sect. 4.1 (field of application) and/or 4.3 (contraindication), those patients will not be included in the follow-up part of the study.

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 stroke and atrial fibrillation

Estimated number of subjects

10000

Study design details

Outcomes

major bleeding event rate within 3 months following the index event, - stroke (hemorrhagic, ischemic or of uncertain classification) - transient ischemic attack (TIA) - systemic/pulmonary embolism - myocardial infarction - life-threatening/gastrointestinal bleeding events - any cause of death (non-vascular, vascular or unknown cause) - point of time/reason of withdrawal/change of medication - compliance/treatment persistance - complications, AE/SAE

Data analysis plan

Analysis of the primary endpoint will be based on the number of major bleeding events within 3 months of follow-up with respect to person-time under medication. For the analysis time-to-event methodology, namely Cox proportional-hazards models, will be used. As change of therapy is allowed during the observation period, each patient can contribute person-time to more than one treatment. As this is the case and risk for major bleeding is assumed

to be higher at the beginning of the observation period than at the end, treatment will be included in the regression model as time-dependent variable, i.e. using counting process syntax. To account for possible confounders of major bleeding, either conventional multiple regression or propensity scores (either as a PS-matched or PS-adjusted analysis) will be used.

Documents

Study results

Prodast_report 15MAR23_final_geschwärzt.pdf (5.95 MB)

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

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