A pharmacoepidemiological study to examine patient characteristics, drug utilization pattern and crude incidence rates of selected outcomes in new users of ticagrelor,clopidogrel and prasugrel in national Swedish registries.

First published: 21/11/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5238

Study ID

22401

DARWIN EU® study

No

Study countries

Sweden

Study description

This is a retrospective cohort study using the Swedish national health registers. Individual data will be linked between registers by the unique personal identification number. All patients aged 20 to 84 years before their first study drug dispensing will be included in the study. In order to capture usual clinical practice no exclusion criteria will be applied. The study period starts the first of June 2011 and continues for one year. Accumulated information on number of ticagrelor exposed subjects will be evaluated after one year and projected information from the observed numbers and crude incidence rates of the selected outcomes will mandate the need to extend the study.Three cohorts will be ascertained, all first time users of ticagrelor and all first time users of clopidogrel and prasugrel, respectively. These three cohorts of first time users will include both patients who have switched from another thienopyridine antiplatelet as well as patients who are thienopyridine antiplatelet naïve at the time of the first study drug dispensing. Individuals with more than one of these three antiplatelet drugs dispensed on the same day will be excluded. The study objectives are to provide a detailed description of patients who are prescribed ticagrelor for the first time and to compare them with patients who are prescribed clopidogrel and prasugrel for the first time, and to estimate potential off-label usage of ticagrelor. The safety objectives of the study are to ascertain incident cases of selected adverse outcomes among new users in the three cohorts of ticagrelor, clopidogrel and prasugrel and to estimate the crude incidence rate of selected adverse outcomes among new users in the three cohorts of ticagrelor, clopidogrel and prasugrel.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Helle Kieler

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2013

Actual: 25/04/2013

Study start date
Planned: 02/12/2013

Actual: 16/12/2013

Data analysis start date
Planned: 01/04/2015

Actual: 01/06/2015

Date of final study report
Planned: 15/09/2015

Actual: 15/11/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To provide a detailed description of patients who are prescribed ticagrelor for the first time

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TICAGRELOR

PRASUGREL

CLOPIDOGREL

Medical condition to be studied

Intracranial haematoma

Gastrointestinal haemorrhage

Bradyarrhythmia

Cardiac pacemaker insertion

Cardiac arrest

Cardiac failure

Acute kidney injury

Liver injury

Dyspnoea

Syncope

Population studied

Short description of the study population

All patients aged 20 to 84 years before their first study drug dispensing were included in 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

Hepatic impaired

Other

Renal impaired

Special population of interest, other

Patients with haemorrhages and cardiac issues

Estimated number of subjects

75000

Study design details

Outcomes

The selected outcomes include hospitalizations for:intracranial bleeding, gastrointestinal bleeding, other bleeding, bradyarrhythmias,pacemaker insertion, cardiac arrest /CHD death outside hospital, heart failure, acute renalfailure and acute liver injury.Selected outcomes not requiring hospitalizations include: dyspnoea, syncope and gout.

Data analysis plan

The patient populations and basic utilization measures will be described. This analysis will in-clude a description of the various subgroups: “naïve”, “non naïve”, “switchers” and “past thienopyridine users”. We will describe duration of treatment over the one year follow-up period in the three study cohorts. First time users of ticagrelor, clopidogrel and prasugrel, respectively will be described with regard to age- and sex distribution, and the prevalence of concomitant treatments and recorded comorbidities. Crude incidence rates and 95% confidence intervals will be estimated as the ratio of the number of cases of the outcome of interest divided by the number of person-years among current users of the study drugs. If numbers permit, event rates in different categories of treatment duration among current users as well as among discontinuers and past users will be reported.

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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Patient Register Sweden, Cause of Death Register Sweden

Data sources (types)

Disease registry

Drug dispensing/prescription data

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

Unknown