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.

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Last updated: 23/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/22401

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 institution and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden
First published: 24/03/2010
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23/04/2024

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

Contact details

Study institution contact
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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 type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Drug utilisation

Data collection methods:
Secondary data collection

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

Data sources

Data source(s)
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