Health outcomes of patients with acute coronary syndromes prescribed ticagrelor in UK primary care: a retrospective cohort study (Outcomes in UK ACS patients prescribed ticagrelor)

First published: 26/04/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17107

Study ID

30120

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Retrospective cohort study using data from Clinical Practice Research Datalink (CPRD). The study cohort includes all patients who received at least one prescription for ticagrelor for the first time between December 2010 and March 2015, following ACS. Patient baseline characteristics will be described: (Age, Gender, Body Mass Index, Smoking status, Sociodemographic status), type of ACS and interventions, CV history and comorbidities, bleeding and respiratory history.The following outcomes will be examined: Incidence of vascular events (composite MI, Stroke, vascular death, specific vascular event and all cause death), incidence of bleeding and incidence of dyspnoea. Time to event for vascular events, bleeding and dyspnoea.

Study status

Finalised

Research institutions and networks

Institutions

AstraZeneca

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Institution

Contact details

Study institution contact

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Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Una Rigney

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/12/2014

Actual: 15/01/2015

Study start date

Planned: 25/02/2016

Actual: 25/02/2016

Data analysis start date

Planned: 31/03/2015

Actual: 31/03/2015

Date of final study report

Planned: 30/05/2018

Actual: 14/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

UK Ticagrelor outcomes study NISP (PASS) D5130R00027 - V3 14March 2016 for ISAC redacted.pdf(416.17 KB)

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

D5130R00027

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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the incidence and time to event for the following in patients treated with ticagrelor in primary care following ACS events:• composite outcome of MI, Stroke or death from vascular causes• individual vascular events (MI, Stroke, and death from vascular causes)• all cause death

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BRILIQUE

Medical condition to be studied

Acute coronary syndrome

Myocardial infarction

Dyspnoea

Cerebrovascular accident

Death

Extravasation blood

Population studied

Short description of the study population

Patients with a first prescription of ticagrelor, between Dec 2010 and July 2014, with a recorded ACS event within the three months prior to and including the index date and no prescription of clopidogrel or prasugrel between the ACS event and first ticagrelor prescription.

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)

Estimated number of subjects

1650

Study design details

Outcomes

To assess the incidence and time to event for the following in patients treated with ticagrelor in primary care following ACS events:• composite outcome of MI, Stroke or death from vascular causes• individual vascular events (MI, Stroke, and death from vascular causes)• all cause death, Rates of vascular events stratified by the following factors• Aged <75 and 75 or older• MI vs UA (Index ACS)• Medically managed vs interventionally managed• Diabetic vs non-diabeticIncidence and time to event for the following:• Bleeding events and stratified by presence/absence of bleeding risk factors • Dyspnoea and stratified by presence/absence of dyspnoea risk factors

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Data analysis plan

Baseline characteristics will be presented for demographics, CV history, ACS type, interventions associated with ACS, prior oral antiplatelet treatment, comorbidities, and secondary prevention treatment. Incidence rates (95% CI) will be presented per 100 patient years for the composite outcome and individual cardiovascular events, bleeding and dyspnoea. Patients will be followed from index date (first prescription for ticagrelor in primary care) for maximum of 12 months. Rates of vascular events will be stratified by the following risk factors: aged <75 years/ ≥75 years, MI vs UA, medically vs interventionally managed, and diabetic vs non-diabetic. Bleeding events will be stratified by presence/absence of bleeding risk factors. Dyspnoea will be stratified by presence or absence of dyspnoea risk factors. Time to first composite event, CV event, time to death, time to first bleeding event and time to first dyspnoea event on therapy will be described in Kaplan-Meier plots.

Documents

Study results

PASS Clinical Study Report D5130R00027_V0.4 14-03-19 redacted.pdf(1.19 MB)

Data management

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Office of National Statistics mortality 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