The Cardiovascular Multi-dimensional Observational Investigation of the Use of PCSK9 Inhibitors (20180059) (cvMOBIUS)

First published: 10/02/2020

Last updated: 13/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS32995

Study ID

36927

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

The purpose of this registry to evaluate the effectiveness of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors to reduce cardiovascular events among subjects presenting with a recent atherosclerotic cardiovascular disease (ASCVD) event in real-world practice. A total of 8500 patients with a recent cardiovascular event who are likely to be eligible for non-statin lipid lowering therapy will be enrolled and followed prospectively for five years. In addition, the study will assess longitudinal patterns of lipid control, clinical outcomes, and LTT including statins, ezetimibe, and PCSK9 inhibitors in adults with an ASCVD event and/or revascularization. This study will also compare the clinical characteristics and outcomes of subjects enrolled in both arms of the registry to understand the strengths and limitations of data harvested directly from electronic health record (EHR) systems as compared with prospectively collected information.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

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Institution

Duke Clinical Research Institute (DCRI)

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Institution

Duke Clinical Research Institute Durham, USA

Contact details

Study institution contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/07/2018

Actual: 28/01/2019

Study start date
Planned: 13/12/2019

Actual: 06/12/2019

Data analysis start date
Planned: 30/10/2026

Date of final study report
Planned: 05/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20180059_ Public Redacted Protocol Amend 2 English.pdf(2.98 MB)

01.02.06 Public Redacted Protocol Ver 1.0 2019-12-06 English.pdf(379.26 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the real-world effectiveness of PCKS9 inhibitors to reduce cardiovascular events in routine practice in a prospective cohort of adults presenting with a recent atherosclerotic cardiovascular disease (ASCVD) event and/or revascularization procedure.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C10AX13) evolocumab

evolocumab

(C10AX14) alirocumab

alirocumab

Medical condition to be studied

Myocardial infarction

Coronary artery disease

Peripheral arterial occlusive disease

Hyperlipidaemia

Ischaemic stroke

Population studied

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

8500

Study design details

Outcomes

Time to event from baseline for the first of all-cause mortality, any non-fatal myocardial infarction, any non-fatal ischemic stroke, The individual components of the primary endpoint, coronary, peripheral or carotid revascularization procedures, major adverse limb events (MALE) including amputation, cardiovascular death, transient ischemic attack (TIA), unstable angina (UA)

Data analysis plan

The primary analysis will use a marginal structural model (MSM) approach to evaluate the relative risk of the primary composite outcome (all-cause mortality, non-fatal MI, and non-fatal IS) in PCSK9i users versus non-users, while accounting for the time varying nature of PCSK9i initiation and discontinuation, and factors related to initiation and discontinuation as they change over time. Following the database lock and prior to the primary effectiveness analysis, we will implement a descriptive analysis to evaluate whether baseline characteristics are balanced between users and non-users of PCSK9is. The primary analysis will parallel an on-treatment analysis, where subjects who discontinue PCSK9i will be censored after six months off therapy. Hazard ratios will be output from a Cox proportional hazards model, weighted by inverse probability to treat weights (IPTW) and inverse probability of censoring weights (IPCW). The same approach will be used for the secondary outcomes

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Electronic health records of enrolled subjects will be obtained from each study site and linked to the prospective registry 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

No