Empagliflozin effectiveness in a real-world population replicating the DECLARE - TIMI58 trial

First published: 09/11/2018

Last updated: 06/12/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS26481

Study ID

32643

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study aims to evaluate the effect of empagliflozin on cardiovascular events and mortality in a real-world population aligned with the trial population, e.g., inclusion and exclusion criteria, of the Dapagliflozin Effect on Cardiovascular Events (DECLARE) - TIMI58 cardiovascular outcome trial using real-world data. This study will produce results on the effect of empagliflozin on cardiovascular events and mortality, which will be directly comparable to the results for dapagliflozin from the DECLARE - TIMI58 trial.

Study status

Ongoing

Research institutions and networks

Institutions

Brigham and Women's Hospital

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Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elisabetta Patorno

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/11/2018

Actual: 06/11/2018

Study start date

Planned: 07/11/2018

Actual: 07/11/2018

Date of final study report

Planned: 31/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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:

Effectiveness study (incl. comparative)

Main study objective:

This study aims to evaluate the effect of empagliflozin on cardiovascular events and mortality in a real-world population aligned with the trial population of the Dapagliflozin Effect on Cardiovascular Events (DECLARE) - TIMI58 cardiovascular outcome trial using real-world data.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

EMPAGLIFLOZIN

Medical condition to be studied

Type 2 diabetes mellitus

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

24000

Study design details

Outcomes

Primary outcomes: MI, stroke, mortality, Secondary outcomes: HF hospitalization, HF hospitalization or mortality

Data analysis plan

We will perform propensity-score (PS) matching and follow patients for each of the outcomes of interest, and estimate measures of effect using person-time based analyses among patients who initiate empagliflozin versus active comparator initiators (e.g. DPP4-i, GLP-1RA). In the adjusted analyses, we will

use propensity score (PS) matching to balance potential confounders. Hazard ratios will be estimated for unmatched and PS-matched population.

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)

Administrative healthcare records (e.g., claims)

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