Prevalence of Cardiovascular Disease in Swedish Patients With Type 2 Diabetes and in Patients Initiating on Empagliflozin

First published: 09/11/2026

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Study Finalised

Administrative details

EU PAS number

EUPAS1000001176

Study ID

1000001176

DARWIN EU® study

No

Study countries

Sweden

Study description

This study aims to describe the prevalence of type 2 diabetes mellitus (T2DM) patients with established cardiovascular disease (CVD) according to the (Empagliflozin) Cardiovascular Outcome Event Trial in Type 2 Diabetes Mellitus Patients (EMPA-REG OUTCOME (ERO)) study definition in a Swedish population.

The aim was also to describe the prevalence of established CVD according to ERO study definition in patients with T2DM who initiates treatment with empagliflozin

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Boehringer Ingelheim

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/04/2018

Study start date

Actual: 02/04/2018

Date of final study report

Actual: 15/11/2018

Study protocol

Prot_SAP_1245-0190.pdf (255.27 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Study design:

Non-interventional, cross-sectional study

Main study objective:

The primary objectives of this study are:

- Prevalence of a history of cardiovascular disease (according to the EMPAREG outcome trial definition)among persons with T2DM who were alive on 31 December 2017
- Prevalence of a history of cardiovascular disease among persons with type 2 diabetes who started empagliflozin treatment between 1 January 2015 and 31 December 2017

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

JARDIANCE

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

EMPAGLIFLOZIN

Additional medical condition(s)

Cardiovascular disease

Population studied

Short description of the study population

The broad study population will include patients with T2DM and at least one registration in the NDR (at any time from start of registry until 2017) and who are alive on 2015-01-01.

Study design details

Summary results

A total of 460 558 patients with T2DM patients who were alive on 2017-12-31 and with at least one registration in the NDR were identified. Patients identified with established cardiovascular disease were 130508 (28,3%), and without cardiovascular disease were 330050 (71,7%). A total of 16985 patients who started with empagliflozin (11,5 %) were identified through SPDR and were also registered as having T2DM in NDR, of which 1952 patients (11,5%) had CVD. The prevalence of T2DM patients with established CVD according to EMPA-REG OUTCOME trial study definition was 28.3%. Corresponding percentage in the patients who initiated on empagliflozin during 2015-2017 was 11.5%.

Documents

Study results

1245-0190_Synopsis.pdf (214.11 KB)

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.

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