CORDIALLY® - CEE: Characteristics of patients with Type 2 Diabetes treated with modern antidiabetic drugs. A real world data collection of patient baseline characteristics, treatment patterns and comorbidities in Central Eastern European (CEE) countries

First published: 28/03/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS28505

Study ID

36466

DARWIN EU® study

No

Study countries

- Bulgaria
- Czechia
- Hungary
- Poland
- Russian Federation
- Serbia
- Slovenia

Study description

This study is initiated 1. To describe and compare T2D patients baseline characteristics when initiating either empagliflozin- or other SGLT2i, DPP4i or GLP1a on top of current antidiabetic treatment by different HCP specialties in CEE countries 2. To describe the burden of comorbidities (prevalence of CVD, CKD) and CVD/CKD risk factors in this T2D patient population at index date 1 3. To describe and compare the actual treatment at study index date 1 in patients with and without established CVD Established CV disease defined as acute myocardial infarction (AMI), cardiology intervention, ischemic heart disease (IHD), congestive heart failure (CHF), peripheral arterial disease (PAD), or stroke. 4. To describe the association of socioeconomic parameters with treatment decisions at index date 1 5. To assess the discontinuation rate, reasons for discontinuation and average duration of treatment for GLP1a, DPP4i and SGLT2i after a follow up of approximately one year from the initial time point (= index date 2)

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 260 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Martin Prázný

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/10/2018

Actual: 24/10/2018

Study start date
Planned: 16/08/2019

Actual: 26/08/2019

Data analysis start date
Planned: 01/07/2021

Actual: 14/04/2021

Date of final study report
Planned: 01/11/2021

Actual: 24/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim RCV GmbH & Co KG

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

Clinicaltrials.gov number: NCT03807440

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Study of association of socioeconomic parameters with treatment decision

Data collection methods:

Secondary use of data

Main study objective:

To describe and compare T2D patients' baseline characteristics when initiating either empagliflozin - or other SGLT2i, DPP4i or GLP1a on top of current antidiabetic treatment by different HCP specialties in CEE countries

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multi-country, multi-site study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BK) Sodium-glucose co-transporter 2 (SGLT2) inhibitors

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

(A10BJ) Glucagon-like peptide-1 (GLP-1) analogues

Glucagon-like peptide-1 (GLP-1) analogues

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with type 2 diabetes mellitus (T2DM) initiated treatment with empagliflozin or other SGLT2i, DPP4i or GLP-1 RA between August 2019 and January 2021 in European countries.

Inclusion criteria:

1. Written informed consent prior to participation
2. Female and male patients age ≥18 years
3. Patients with T2D diagnosis
4. Patients who have been initiated (first ever use) with empagliflozin or other SGLT2i, DPP4i or GLP-1 RA between September 2018 and December 2018 (study index date 1)
5. Patients who have been naive to treatment with empagliflozin or other SGLT2i, DPP4i or GLP-1 RA at study index date 1

Exclusion criteria:

1. Patients age <18 years
2. Patients diagnosis of other types of diabetes than T2D
3. Patients who do not provide written consent to the terms of 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

Other

Special population of interest, other

Patients with type 2 diabetes mellitus

Estimated number of subjects

4000

Study design details

Outcomes

T2D patients’ baseline characteristics when initiating either empagliflozin - or other SGLT2i, DPP4i or GLP1a on top of current antidiabetic treatment by different HCP specialties in CEE countries., Burden of comorbidities (prevalence of CVD, CKD and CVD/CKD risk factors) (index date 1) - Actual treatment use (index date 1) in patients with/without established CVD - Association of socioeconomic parameters with treatment decisions (index date 1) - Discontinuation rate of actual treatment (index date 2), reasons for discontinuation and average treatment duration for GLP1a, DPP4i and SGLT2

Data analysis plan

All analyses in this study are descriptive; results are to be interpreted in an explorative manner. For categorical variables summary tabulations of the number and percentage within each category (with a category for missing data) of the parameter will be presented. For continuous variables number of values, mean, standard deviation, minimum, median, maximum and number of missing values will be presented. Incidence rates and 95% CI will be given when appropriate.

Documents

Study results

1245-0187-CORDIALLY_CSR_final V1.0_Abstract.pdf (5.27 MB)

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)

Other

Data sources (types), other

Data will be collected retrospectively from existing patient data (medical chart review) previously documented by health care professionals during routine practice in patients treated for T2D in an endocrinologist, diabetologist or cardiologist office based setting (nonhospital).

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