Clinical outcomes of novel antidiabetic medicines: Real-world evidence from Slovenian population-based study (CONAMS)

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Study Finalised

Administrative details

EU PAS number

EUPAS32558

Study ID

43742

DARWIN EU® study

No

Study countries

Slovenia

Study description

Two studies will be performed using real-world data from administrative claims databases in Slovenia. First retrospective cohort study will evaluate the risk of cardiovascular events in patients with type 2 diabetes using different classes of antidiabetic medicines. Second retrospective cohort study will examine the risk of amputations in patients with type 2 diabetes treated with SGLT-2 inhibitors compared to those treated with DPP-4 inhibitors.

Study status

Finalised

Research institutions and networks

Institutions

Department of Social Pharmacy, Faculty of pharmacy, University of Ljubljana

Slovenia

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Institution **Educational Institution**

Contact details

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Primary lead investigator

Spela Zerovnik

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/10/2017

Study start date

Actual: 30/07/2019

Data analysis start date

Planned: 13/01/2020

Actual: 01/07/2020

Date of final study report

Planned: 30/06/2020

Actual: 30/09/2021

Sources of funding

- Other

More details on funding

Young researchers' training programme funded by Slovenian Research Agency (Programme Group No. P1-0189).

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

First retrospective cohort study: to evaluate the effect of SGLT2 inhibitors and GLP-1 analogues compared with DPP-4 inhibitors on cardiovascular morbidity and mortality in patients with type 2 diabetes. Second retrospective cohort study: to compare the risk of amputation in patients with type 2 diabetes who were treated with SGLT2 inhibitors to those treated with DPP-4 inhibitors.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

(A10BA) Biguanides

Biguanides

(A10BB) Sulfonylureas

Sulfonylureas

(A10BD) Combinations of oral blood glucose lowering drugs

Combinations of oral blood glucose lowering drugs

(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

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

Sodium-glucose co-transporter 2 (SGLT2) inhibitors

(A10BX) Other blood glucose lowering drugs, excl. insulins

Other blood glucose lowering drugs, excl. insulins

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Patients with type 2 diabetes treated with SGLT-2 inhibitors compared to those treated with DPP-4 inhibitors.

The database population consisted of all patients who filled at least two prescriptions for any antidiabetic medicine within 1 year prior to 30 June 2014. To minimise inclusion of patients with type 1 diabetes, gestational diabetes, or early-onset type 2 diabetes, we limited patient selection to those aged 40 years or older. From this patient population, we selected new users of SGLT2i or DPP-4i between 30 June 2014 and 30 June 2018 (recruitment period). To limit the sample to new users of SGLT2i or DPP-4i, we excluded patients treated with SGLT2i, DPP-4i, or GLP-1RA at any time before the index date. The inclusion period started on 30 June 2014, the date when the first drug from the SGLT2i group became available on the Slovenian market.

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

Type 2 diabetes mellitus patients

Estimated number of subjects

10.000

Study design details

Outcomes

First retrospective cohort study: occurrence of major adverse cardiovascular events as a composite endpoint (hospitalisations with a main diagnosis of myocardial infarction or ischemic stroke or cardiovascular death), hospitalisations due to heart failure, cardiovascular death and all-cause death. Second retrospective cohort study: occurrence of lower extremity amputations.

Data analysis plan

First retrospective cohort study: a Cox regression model will be used to evaluate the effects of the antidiabetic medicine group on the risk of each outcome. Other variables will also be included in the regression model, such as patient age, gender, concomitant medications, duration of type 2 diabetes, etc. The primary analysis will be based on the “intention-to-treat” population and the secondary analysis will be performed on the “on-treatment” population. Second retrospective cohort study: patients from the SGLT2 inhibitor group and the DPP-4 inhibitor group will be matched in a 1:1 ratio using propensity score matching. A Cox regression model will be used to estimate hazard ratios for amputations in new users of SGLT2 inhibitors compared to new users of DPP-4 inhibitors.

Documents

Study publications

Zerovnik, S., Kos, M. & Locatelli, I. Risk of lower extremity amputations in pa...

Zerovnik S, Kos M, Locatelli I. Cardiovascular morbidity and mortality in patie...

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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