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

**First published:** 03/12/2019

**Last updated:** 18/10/2021

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

**First published:** 15/12/2021

**Last updated:** 20/08/2024

**Institution** **Educational Institution**

# Contact details

**Study institution contact**

Igor Locatelli igor.locatelli@ffa.uni-lj.si

**Study contact**

igor.locatelli@ffa.uni-lj.si

**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**

10000

## 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

## 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)

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