The effect of SGLT2 inhibitors among patients with Type 2 diabetes on the incidence of colorectal cancer

First published: 28/01/2026

Last updated: 28/01/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000920

Study ID

1000000920

DARWIN EU® study

No

Study countries

Germany

Study description

The diabetes medication class of SGLT2 inhibitors (SGLT2i) has been shown to not only improve glycaemic control in type 2 diabetes patients, but also provide cardiovascular benefit in both diabetic patients and patients with heart failure, as well as renal benefit. Recent nonclinical research results have additionally suggested a potential benefit in reducing colorectal tumour growth. A retrospective cohort study from Hong Kong has supported this claim by estimating a reduced risk of incident colorectal cancer (CRC) for SGLT2i users compared to DPP4 inhibitor (DPP4i) users. Two Asian multi-outcome database studies suggest a similar protective effect.

This study aims to estimate the causal effect of initiating treatment with SGLT2i versus DPP4i additionally to metformin therapy in persons with type 2 diabetes. It is designed as a cohort study based on German health insurance claims data from the years 2009 – 2023; targeted maximum likelihood estimation for survival & competing risk analysis will be used to estimate absolute CRC-specific risk curves for both treatment groups and 5-year average treatment effects will be estimated.

Study status

Planned

Research institutions and networks

Institutions

Pharmacoepidemiology Research, Federal Institute for Drugs and Medical Devices (BfArM)

Germany

First published: 02/06/2023

Last updated: 23/04/2024

Institution | Regulatory Authority | ENCePP partner

Contact details

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 05/11/2022

Actual: 11/11/2022

Study start date

Planned: 30/04/2026

Date of final study report

Planned: 31/10/2026

Sources of funding

- EU institutional research programme

More details on funding

HORIZON Europe

Study protocol

Study_protocol_v1_clean.pdf (466.21 KB)

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Study Design

Non-interventional study design

Cohort

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

Medical condition to be studied

Colorectal cancer

Population studied

Short description of the study population

Persons with Type 2 diabetes already using metformin, at least 30 years of age, who have never been diagnosed with cancer (excl. non-melanoma skin cancer) and have never been treated with SGLT2 inhibitors or DPP4 inhibitors (or GLP1 receptor agonists in supplementary analysis) before study entry

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Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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 source(s), other

Health Data Lab (Forschungsdatenzentrum Gesundheit, Germany)

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

Unknown