A Pan-European Post-Authorisation Safety Study: Risk of Pancreatic Cancer Among Type 2 Diabetes Patients who Initiated Exenatide as Compared with those who Initiated Other non-Glucagon-Like Peptide 1 Receptor Agonists based Glucose Lowering Drugs (EXCEED)

First published: 06/04/2021

Last updated: 24/10/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS31458

Study ID

49324

DARWIN EU® study

No

Study countries

Denmark

Finland

France

Norway

Spain

Sweden

United Kingdom

Study description

EXCEED is a non-interventional post-authorisation safety study aiming to assess the risk of developing pancreatic cancer among type 2 diabetes mellitus (T2DM) patients who initiated exenatide compared to those who initiated other non-glucagon like peptide 1 receptor agonists (GLP-1 RA) based glucose lowering drugs (GLDs). Study data will be collected from secondary data sources across 7 European countries. The study will be conducted as a multi-country, long-term, retrospective, observational database study. Initiators of exenatide will be matched to initiators of non-GLP-1 RA based GLDs (comparator group) based on propensity score and calendar period of study entry. All analyses for pancreatic cancer will be conducted in the matched study population using an “intention-to-treat” approach. The study will use information from 8 data sources in 7 European countries (France, Spain, The United Kingdom, Finland, Denmark, Norway, and Sweden). Patients with T2DM, aged 18 years or older, who initiated treatment with exenatide or non-GLP-1 RA based GLDs during the study period, 2006 to 2023, will be included. Exposure to exenatide and non-GLP-1 RA based GLDs will be ascertained from recordings of prescriptions or insurance claims registrations as available in the different data sources. The outcome of pancreatic cancer will be defined as a primary diagnosis of pancreatic cancer during follow-up.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

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Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fabian Hoti

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/06/2019

Actual: 17/06/2019

Study start date
Planned: 01/01/2024

Actual: 24/09/2024

Data analysis start date
Planned: 01/01/2024

Actual: 30/09/2024

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

EXCEED_PASS Protocol_V2.0_20 Mar 2020_SIGNED_redacted.pdf (2.53 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To estimate the incidence rate and hazard ratio for pancreatic cancer associated with exposure to exenatide (BYETTA or BYDUREON/ BYDUREON BCise), compared with exposure to non-Glucagon Like Peptide-1 Receptor Agonist based Glucose Lowering Drugs, among patients with Type 2 Diabetes Mellitus.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

EXENATIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ01) exenatide

exenatide

Medical condition to be studied

Type 2 diabetes mellitus

Pancreatic carcinoma

Population studied

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)

Estimated number of subjects

350000

Study design details

Outcomes

Pancreatic cancer

Data analysis plan

The incidence rate of pancreatic cancer will be estimated for the exenatide group and the comparator group in each of the 8 data sources. For the analysis of the primary objective, Cox proportional hazards regression will be used to estimate the hazard ratio (with 95% confidence interval) for time to pancreatic cancer, comparing patients in the exenatide group to the comparator group by the ‘intention-to-treat” approach. In secondary analysis of the primary objective, the association between cumulative use of exenatide and pancreatic cancer will also be assessed. The analyses will be conducted for each data source separately and combined using meta-analyses, providing a summary estimate for all data sources.

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)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

The Norwegian Prescribed Drug Registry

Data source(s), other

Drugs and Pregnancy Finland, eDRIS

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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