Incidence of Pancreatic Malignancy and Thyroid Neoplasm in Type 2 Diabetes Mellitus Patients who Initiate Exenatide Compared to Other Antihyperglycemic Drugs - Phase 2 (Extended Accrual and Follow-Up)

First published: 06/07/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13956

Study ID

24671

DARWIN EU® study

No

Study countries

United States

Study description

This is a retrospective cohort study that compares incidence rates of pancreatic cancer and thyroid neoplasm between initiators of exenatide and initiators of other antidiabetic drugs using 2 administrative databases from commercial health plans in the US. The study cohorts will be created to include patients accrued from 01 June 2005 through 30 June 2015 in Optum Research Database and 31 March 2015 in Impact National Benchmark Database. Initiators will be matched 1:1 or 1:2 (exenatide:Others) on propensity scores within 6-month calendar blocks.The matched cohorts, when aggregated, will form the analytic population. The analyses of outcomes will account for the source databases and matching ratios through statistical conditioning. Data from the 2 databases will be combined to increase statistical precision. Pancreatic cancer and thyroid neoplasm will be identified via patterns of claims using algorithms applied in the previous study. A validation of the algorithms will be conducted within a sample of medical records of patients in the Optum Research Database. Clinical characteristics that are captured poorly in the claims data will be abstracted from the medical records. Estimation of effects will involve time-fixed and time-dependent, cumulative classifications of exposure. A nested case-control analysis will also be performed to account for potential confounders that are captured poorly in the claims data, if sample size allows.

Study status

Finalised

Research institutions and networks

Institutions

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Contact details

Study institution contact

Caihua Liang ClinicalTrialTransparency@astrazeneca.com

Study contact

ClinicalTrialTransparency@astrazeneca.com

Primary lead investigator

Caihua Liang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/10/2014

Actual: 24/10/2014

Study start date

Planned: 03/03/2016

Actual: 03/03/2016

Data analysis start date
Planned: 03/03/2016

Actual: 03/03/2016

Date of final study report
Planned: 01/11/2017

Actual: 17/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

Redacted protocol BO15.pdf (746.88 KB)

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)

Other study registration identification numbers and links

D5550R00003

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives are to estimate the absolute and relative incidence of pancreatic cancer and thyroid cancer that occurs at least one year after initiation of exenatide twice daily or once weekly or initiation of other antidiabetic drugs—overall and by duration of follow-up and duration of

exposure.

Study Design

Non-interventional study design

Case-control

Other

Non-interventional study design, other

Retrospective cohort study

Study drug and medical condition

Medicinal product name

BYDUREON

BYETTA

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

EXENATIDE

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Patients with Type 2 Diabetes Mellitus who had at least 9 months of continuous enrollment in their health plan between 01 September 2004 and 31 December 2015.
Eligible patients will have:
• Complete medical and pharmacy benefits and at least 9 months of continuous enrollment in the health plan prior to the cohort entry date
• A diagnosis of T2D (ICD-9-CM 250.x0, 250.x2) during the 9-month baseline period, inclusive of the cohort entry date
• A dispensing of at least one antidiabetic drug other than the initiating drug during the 9- month baseline period, inclusive of the cohort entry date

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

Diabetes mellitus patients

Estimated number of subjects

523741

Study design details

Outcomes

The primary outcomes are newly diagnosed pancreatic cancer and thyroid cancer occurring at least one year following cohort entry. The secondary outcomes are newly diagnosed benign thyroid neoplasm, medullary thyroid carcinoma, and non-medullary thyroid carcinoma occurring at least one year following cohort entry.

Data analysis plan

An “intent-to-treat” analysis will be conducted that holds the original exposure assignment constant from the date of accrual through the end of follow-up. At-risk person-time will be accrued from one year post drug initiation until the earliest occurrence of an outcome, health plan disenrollment, or end of study period. Hazard ratios and 95% confidence intervals of newly diagnosed pancreatic cancer or thyroid cancer will be estimated. To estimate the cumulative effect of exenatide exposure on the outcomes Analysis of Cumulative Exposure will also be conducted. A nested case-control study design will be applied to account for potential confounders that are poorly captured in the claims data. The cases will consist of all chart-confirmed cases of pancreatic or thyroid cancers in the propensity-matched exenatide and comparison cohorts from the Optum Research Database. Controls without cancers will be selected from the same source cohorts that gave rise to the cases.

Documents

Study results

D5550R00003 (EUPAS13956) Revised Final Report 17APR2018_AZ_Redacted.pdf (4.07 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)

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