Incidence of Pancreatic Malignancy and Thyroid Neoplasm in Type 2 Diabetes Mellitus Patients who Initiate Exenatide Compared to Other Antihyperglycemic Drugs. (B015)

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Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3614

Study ID

20439

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study was to assess incident pancreatic and thyroid cancers among patients who initiated exenatide as compared to patients who initiated other second line use antidiabetes drugs. This was a large population-based retrospective cohort study using data from two large administrative databases in the United States from 2005 to 2010. Medical chart validated claims based algorithms were used to identify incident outcomes. Outcomes were assessed starting one-year post index drug exposure. Propensity score matching and multivariate modeling were used to adjust for cohort differences. After selection criteria, there were 18,932 initiators of exenatide and 27,691 matched initiators of other antihyperglycemic drugs across both databases, with a total of 10 and 11 pancreatic cancer cases and 16 and 16 thyroid cancer cases, respectively. For pancreatic cancer there was no significant difference between study cohorts in either database assessed (HR=1.4, 95%CI=0.4-4.2, HR=0.8, 95%CI=0.2-3.6). For thyroid cancer, results were also non-significant in both databases (HR=2.0, 95%CI=0.7-5.6, HR=1.3, 95%CI=0.5-3.4). Additional analyses were conducted stratifying by follow-up time, exposure duration, and cumulative dose. Given the small numbers in several fo these strata, no conclusions were made regarding this data. In conclusion, these analyses do not support nor refute the presence of an increased incidence of pancreatic or thyroid cancers amogn exenatide initiators when compared to other antihyperglycemic drugs initiators. There were differences in the direction and strength of point estimates between the two different databases. Determining the underlying reasons (e.g., chance, unmeasured confounding, detection bias, and/or protopathic bias) for variability is challenging given the small number of outcomes observed.

Study status

Finalised

Research institutions and networks

Institutions

Optum

Germany

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Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stephen Motsko

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/03/2011

Actual: 02/03/2011

Study start date
Planned: 01/05/2011

Actual: 01/05/2011

Date of final study report
Planned: 19/12/2012

Actual: 19/12/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

Exenatide_Final_Report_Updated_17MAY2013_ENCEPP.pdf (677.2 KB)

Exenatide Revised Final Report-25JUL2013.pdf (768.32 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)

Methodological aspects

Study type

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 objective of this study was to estimate the absolute and relative incidence of newly diagnosed pancreatic and thyroid cancers among initiators of exenatide compared to matched initiators of other antihyperglycemic agents, overall and by duration of follow-up and drug exposure, assessing events one-year after drug initiation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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 included in the Life Sciences Research Database (LSRD) or the Impact database with at least 9 months of continuous enrollment in the underlying health insurance plan between 01 September 2004 and 31July 2010. Patients were eligible for cohort entry starting on 01 June 2005 (the date of exenatide launch).

Patients who had complete medical and pharmacy benefits and 9 months of continuous enrollment in the health plan prior to cohort entry date, and had a diagnosis of T2D (ICD-9-CM 250.x0, 250.x2) during the 9-month baseline period, inclusive of the cohort entry date, and had a dispensing of at least one antidiabetes drug other than the initiating drug during the 9-month baseline period, inclusive of the cohort entry date were included.

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

Diabetes mellitus patients

Estimated number of subjects

46.623

Study design details

Outcomes

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

Data analysis plan

The outcomes of interest were identified on the basis of algorithms consisting of specific patterns of health insurance claims data. The algorithms were validated against a set of cases that were initially identified from the claims data and confirmed through medical chart review. Patients were followed for a new occurrence of pancreatic cancer or thyroid neoplasm from one-year after drug initiation to the end of follow-up period (31/12/2010) or disenrollment from the health plan. Two approaches were used to estimate the absolute and relative incidence of pancreatic cancer and thyroid neoplasm between the study cohorts. The first, a time-fixed analysis, categorized all follow-up time according to the initial exposure status (i.e. the patient's first dispensing). The second approach involved measuring cumulative dose and duration of exenatide exposure.

Data management

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