Dulaglutide and Potential Risks of Pancreatic Cancer and Thyroid Cancer: A Non-Interventional PASS (H9X-MC-B013)

First published: 24/11/2021

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49022

EU PAS number

EUPAS32646

Study ID

49022

DARWIN EU® study

No

Study countries

☐ Finland

Sweden

Study description

This study is a retrospective, non-interventional post-authorization safety study that uses real-world data from two European countries (Sweden and Finland) to evaluate the incidence of pancreatic cancer and thyroid cancer in association with dulaglutide treatment compared to other second-line anti-diabetes medications among patients with T2DM.

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

Yuanyuan Wang

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 07/11/2019

Study start date
Planned: 31/01/2022

Actual: 01/06/2024

Date of interim report, if expected
Planned: 31/12/2025

Date of final study report
Planned: 31/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Co.

Study protocol

B013 05 Protocol (a)_Redacted.pdf(5.12 MB)

LY2189265 Dulaglutide B013 (e) NI PASS Protocol _Redacted.pdf(589.53 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Data collection methods:

Primary data collection

Study design:

Retrospective, non-interventional post-authorization safety study

Main study objective:

To estimate the incidence rates and evaluate the potential association of pancreatic cancer and thyroid cancer (including subtypes: Papillary, Follicular, and Medullary C-cell tumor) for patients with T2DM who initiated dulaglutide compared to those who initiated other non-incretin second-line ADMs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TRULICITY

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

DULAGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ05) dulaglutide

dulaglutide

Medical condition to be studied

Pancreatic carcinoma

Thyroid cancer

Population studied

Short description of the study population

Adult patients with confirmed diagnosis of T2DM who initiated a second-line antidiabetic medication (ADM) during the observation period and met the related inclusion and exclusion criteria within this study.

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)

Estimated number of subjects

325000

Study design details

Setting

This study will be conducted using national health registries, including data collected in outpatient and inpatient settings from Sweden and Finland.

Comparators

Comparison 1: dulaglutide initiators compared to non-incretin second-line ADM initiators

Comparison 2: dulaglutide initiators compared to other GLP-1 RA initiators (excluding dulaglutide), and

Comparison 3: all GLP-1 RA initiators compared to non-incretin second-line ADM initiators.

Outcomes

Pancreatic cancer, thyroid cancer (including subtypes: Papillary, Follicular, and Medullary [C-cell tumour])

Data analysis plan

The primary analysis will be an intention to treat (ITT) approach, in which pancreatic cancer and thyroid cancer will be assessed any time after the end of an exposure latency period of 3-years.

Cox proportional hazards regression with matching on the exposure propensity score (EPS) to control for the potential confounders will be applied to compare exposure groups with respect to the outcomes of interest.

Data management

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Sweden National Cancer Register / Cancerregistret

Swedish Cause of Death Register

Terveydenhuollon hoitoilmoitusrekisteri (Finland Care Register for Health Care)

Data source(s), other

Sweden National Registries used: the Swedish National Patient Register, the Swedish Prescribed Drug Register, National Cancer Registry, the National Diabetes Register, the National Cause of Death Register, and the Total Population Register;
Finland National Registries used: the Finnish Care Register for Health Care (HILMO), the Register of Primary Health Care Visits (AvoHILMO), the Finnish Prescription Registers, the Finnish Cancer Registry, the Finnish Causes of Death Register, Register of Completed Education and Degrees, the Population Register, the Special Refunds Entitlement Register and regional laboratory data;

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No