Pancreatic Cancer and Thyroid Cancer Risks with Dulaglutide Treatment

First published: 14/01/2022

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45173

EU PAS number

EUPAS45172

Study ID

45173

DARWIN EU® study

No

Study countries

Finland

Sweden

United Kingdom

United States

Study description

A non-interventional study aims to evaluate the association of dulaglutide, a long-acting glucagon-like peptide-1 receptor agonist, with pancreatic cancer and thyroid cancer, including medullary thyroid carcinoma. Adults with type 2 diabetes who initiated dulaglutide will be compared to those who initiated other second-line anti-hyperglycemic drugs.

Study status

Planned

Research institution and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Ayad Ali

Study contact

ayadali@fulbrightmail.org

Primary lead investigator

Ayad Ali

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/01/2018

Actual: 31/01/2018

Study start date

Planned: 31/01/2022

Data analysis start date

Planned: 31/01/2023

Date of interim report, if expected

Planned: 31/12/2024

Date of final study report

Planned: 31/12/2030

Sources of funding

- EU institutional research programme
- Other

More details on funding

Eli Lilly and Company

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

Compare the risks of pancreatic cancer among initiators of dulaglutide compared to initiators of other second-line anti-hyperglycemic drugs. Compare the risks of thyroid cancer (including medullary thyroid carcinoma) among initiators of dulaglutide compared to initiators of other second-line anti-hyperglycemic drugs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DULAGLUTIDE

Medical condition to be studied

Diabetes mellitus

Additional medical condition(s)

Type 2 Diabetes Mellitus

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

140000

Study design details

Outcomes

Pancreatic Cancer Thyroid Cancer, Medullary Thyroid Carcinoma

Data analysis plan

Propensity Matched and High-Dimensional Propensity Analyses will be applied to estimate Hazard Ratios and Confidence Intervals.

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Military Health System Data Repository United States, Drugs and Pregnancy Finland

Data sources (types)

Administrative data (e.g. claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Exposure registry

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