

# Pancreatic Cancer and Thyroid Cancer Risks with Dulaglutide Treatment

**First published:** 14/01/2022

**Last updated:** 23/04/2024

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 institutions and networks

### Institutions

**IQVIA**

☐ United Kingdom

**First published:** 12/11/2021

**Last updated:** 22/04/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Ayad Ali

**Study contact**

[ayadali@fulbrightmail.org](mailto: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 healthcare records \(e.g., claims\)](#)

[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