

# Pancreatic Cancer and Thyroid Cancer Risks with Dulaglutide Treatment

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

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

Study

Planned

## Administrative details

### EU PAS number

EUPAS45172

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### Study ID

45173

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### DARWIN EU® study

No

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### Study countries

- ☐ Finland
  - ☐ Sweden
  - ☐ United Kingdom
  - ☐ United States
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## 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.

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## Study status

Planned

# 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

Ayad Ali [ayadali@fulbrightmail.org](mailto:ayadali@fulbrightmail.org)

**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

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### Study start date

Planned: 31/01/2022

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### Data analysis start date

Planned: 31/01/2023

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### Date of interim report, if expected

Planned: 31/12/2024

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### Date of final study report

Planned: 31/12/2030

## Sources of funding

- EU institutional research programme
- Other

## More details on funding

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **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

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#### **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

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### **Medical condition to be studied**

Diabetes mellitus

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### **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)

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## **Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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## **Estimated number of subjects**

140000

# Study design details

## **Outcomes**

Pancreatic Cancer Thyroid Cancer, Medullary Thyroid Carcinoma

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## **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

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**Data source(s), other**

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

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**Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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**Data sources (types), other**

Exposure registry

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No