# Incidence of Thyroid Neoplasm and Pancreatic Cancer in Type 2 Diabetes Mellitus Patients who Initiate Once Weekly Exenatide Compared with Other Antihyperglycemic Drugs

**First published:** 30/06/2016

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Study Discontinued

## Administrative details

**EU PAS number**

EUPAS13904

**Study ID**

19186

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

The study is intended to monitor the occurrence of thyroid neoplasm and pancreatic cancers with weekly exenatide. Anonymised electronic health care records will be used to monitor the weekly exenatide users and compare them to patients using other types of medication

**Study status**

Discontinued

## Contact details

**Study institution contact**

Tarita Murray-Thomas
ClinicalTrialTransparency@astrazeneca.com

**Study contact**

ClinicalTrialTransparency@astrazeneca.com

**Primary lead investigator**

Tarita Murray-Thomas

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 07/11/2013

**Study start date**

Actual: 01/07/2011

**Data analysis start date**
Actual: 10/11/2013

**Date of final study report**
Actual: 29/09/2014

## Sources of funding

## More details on funding

AstraZeneca

## Study protocol

Redacted protocol BO17.pdf (477.06 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)

## Other study registration identification numbers and links

D5551N00007

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

Retrospective cohort study

**Main study objective:**

The objective of this study is to estimate and compare the incidence of thyroid neoplasm and pancreatic cancer among initiators of exenatide once weekly compared with users of other oral antidiabetic agents.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

BYDUREON

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

EXENATIDE

**Anatomical Therapeutic Chemical (ATC) code**

(A10BJ01) exenatide

exenatide

**Medical condition to be studied**

Type 2 diabetes mellitus

Thyroid neoplasm

Pancreatic carcinoma

# Population studied

**Short description of the study population**

The study cohort will consist of adults aged 18 years and older with a diagnosis of diabetes mellitus as recorded in the medical record. Patients with a record of type I diabetes will be excluded.

**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)

**Estimated number of subjects**

55.000

# Study design details

**Comparators**

Users of other oral antidiabetic agents

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**Outcomes**

Incidence of thyroid neoplasm and pancreatic cancer. To describe the incidence of medullary thyroid cancer (MTC) among initiators of exenatide once weekly and matched control cohort of other anti-diabetic drugs.To estimate the incidence of new-onset benign thyroid neoplasm among initiators of exenatide once weekly compared to a matched control cohort of other anti-diabetic drugs.

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**Data analysis plan**

Risk of cancers in relation to the exposure to exenatide once weekly will be estimated in terms of incidence and relative risk as compared with exposure to other anti-diabetic treatment. Patients will be matched based on their baseline characteristics. Intent-to-treat analysis will be performed using Cox regression analysis. Time-dependent analysis will be additionally conducted based on current and past exposure to the study drugs.

## Documents

**Abstract of study report**

Redacted D5551N00007 Study Report.pdf (1.08 MB)

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

# Data sources

**Data source(s)**

Clinical Practice Research Datalink

**Data sources (types)**

Electronic healthcare records (EHR)

# 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