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

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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

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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

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

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

55000

Study design details

Comparators

Users of other oral antidiabetic agents

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.

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