An Observational Study of the Risk of Malignant Neoplasms and Malignant Neoplasms of Special Interest (Thyroid and Pancreatic Cancer) in Subjects Treated with Albiglutide Compared to Those Treated with Other Antidiabetic Agents (201805)

First published: 15/12/2015

Last updated: 14/08/2020

Study Finalised

Administrative details

EU PAS number

EUPAS11850

Study ID

36771

DARWIN EU® study

No

Study countries

United Kingdom

Study description

With the cancellation of the Eperzan EU MA in January 2019, this post marketing study is no longer required or feasible to conduct. This study is a nested case control study and uses the Clinical Practice Research Datalink (CPRD) of the U.K. The diabetes cohort will include type 2 diabetic subjects aged ≥ 18 years old who are “new users” of an antidiabetic agent (ADA) as of when albiglutide is fully launched in the UK. The study compares the risk of malignant neoplasms of special interest (thyroid and pancreatic cancer) in subjects prescribed albiglutide, and albiglutide in combination with insulin, to other antidiabetic agent and insulin, respectively. It also compares the risk of the most common malignant neoplams in subjects prescribed albiglutide in combination with insulin compared to insulin. Analysis will be conducted when approximately 10,000 albiglutide prescribed subjects, with a minimum follow-up duration of one year each, have accrued in the database. Conditional logistic regression will be used to estimate odds ratios and 95% confidence intervals (CIs) of the malignant neoplasms of special interest and the common malignant neoplasms associated with the use of albiglutide compared to other antidiabetic agents.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/11/2015

Actual: 18/11/2015

Study start date

Planned: 01/01/2018

Actual: 18/11/2015

Date of final study report
Planned: 27/11/2024

Actual: 10/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201805-protocol-redact.pdf(505.36 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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

1.Compare the risk of malignant neoplasms (MN) of special interest (thyroid and pancreatic) in subjects prescribed albiglutide to other antidiabetic agents2.Compare the risk of MN of special interest in subjects prescribed albiglutide with insulin, to insulin3.Compare the risk of most common MN (breast, prostate, colorectal and lung) in subjects prescribed albiglutide with insulin, to insulin.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Name of medicine

EPERZAN

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

ALBIGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

The diabetes cohort will include type 2 diabetes subjects aged ≥ 18 years old at cohort entry and who had at least three consecutive new prescription for the same antidiabetic agent in the Clinical Practice Research Datalink (CPRD) when albiglutide will be fully launced in the U.K.

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

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

10000

Study design details

Outcomes

Malignant neoplasms of special interest (thyroid and pancreatic cancer). Other common malignant neoplasms (breast, prostate, colorectal, and lung cancers).

Data analysis plan

Conditional logistic regression will be used to estimate odds ratios along with 95% confidence intervals (CIs) of the malignant neoplasms of special interest and the common malignant neoplasms associated with the use of albiglutide compared to other antidiabetic agents. Separate conditional logistic regression models will be run for the various objectives of the study, providing likelihood ratios for the cancers of special interest as well as the most common malignant neoplasms. For the cancers of special interest, subjects ever exposed to albiglutide will be compared to subjects exposed to other antidiabetic agents. For the common malignant neoplasms, subjects ever exposed to albiglutide in combination with insulin will be compared to those exposed to insulin.

Data management

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