An Observational Study of the Risk of Acute Pancreatitis in Subjects Exposed to Albiglutide, Other GLP-1 Agonists or DPP-4 Inhibitors Compared to Other Antidiabetic Agents (201804)

First published: 27/01/2016

Last updated: 18/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11845

Study ID

48256

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study is a retrospective cohort study and will be conducted in the Truven Marketscan Commercial health insurance database. The study will: 1) evaluate the association between albiglutide and acute pancreatitis as compared to the association observed between this outcome and use of other antidiabetic agents (ADAs) (excluding GLP-1 agonists and DPP-4 inhibitors) and 2) evaluate the association between GLP-1 agonists (including and excluding albiglutide), DPP-4 inhibitors and acute pancreatitis as compared to the association observed between this outcome and use of other ADAs. The analysis will be conducted when 5000 and again when 31,000 subjects are exposed to albiglutide in this database. Unadjusted incidence rates of acute pancreatitis will be calculated for each exposure group. Time to acute pancreatitis will be assessed using Kaplan Meier survival curves with log rank test. Cox Proportional Hazards modeling will be used to compare the adjusted risk of acute pancreatitis among subjects treated with albiglutide, GLP-1 agonists excluding albiglutide, GLP-1 agonists including albiglutide, and DPP-4 inhibitors compared to other ADAs (reference group).

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: 25/07/2014

Actual: 01/05/2017

Date of final study report

Planned: 22/05/2019

Actual: 23/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-201804-protocol-redact.pdf(6.79 MB)

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:

Disease /health condition

Human medicinal product

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 association between albiglutide and acute pancreatitis to other antidiabetic agents (ADAs) (excluding GLP-1 agonists and DPP-4 inhibitors).2. Evaluate the association between GLP-1 agonists (including and excluding albiglutide), DPP-4 inhibitors and acute pancreatitis as compared to the association observed between this outcome and use of other ADAs.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Name of medicine

EPERZAN

Name of medicine, other

Tanzeum

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 study used the Truven Marketscan Commercial database to analyze the use of albiglutide in treating type 2 diabetes (T2D). The study population included individuals aged 18-64 years, enrolled in a health plan for at least 6 months, with at least one type 2 diabetes (T2D) diagnosis claim and two consecutive prescription claims for a new antidiabetic agents (ADA) from April 15, 2014, to September 30, 2016.

Inclusion criteria:

1. Patients with at least one claim of T2D diagnosis in database
2. Patients with gestational diabetes
3. Patients with at least one antidiabetic medication starting from April 15, 2014

4. Limit age 18-64 years old

5. Patients who continuously enrolled and have pharmacy coverage in the health plan for ≥6 months prior index date

6. Patients who have at least two consecutive prescription claims

7. Patients who are a new user (based on group level)

Exclusion criteria:

1. Exclude the patients who have evidence of pancreatitis disease in the pre-index period

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Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Patients with type 2 diabetes mellitus

Estimated number of subjects

5000

Study design details

Outcomes

Acute pancreatitis identified in the post-index follow up period by hospitalization claims containing ICD-9 code 577.0 (acute pancreatitis) as a primary discharge diagnosis. Time to acute pancreatitis

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Data analysis plan

Unadjusted incidence rates (along with 95% confidence interval) of acute pancreatitis will be calculated for the each exposure group. Differences in exposure groups of time to acute pancreatitis will be assessed using Kaplan Meier survival curves with log rank test. Cox Proportional Hazards modeling will be used to compare the adjusted risk of acute pancreatitis among subjects treated with albiglutide, GLP-1 agonists excluding albiglutide, GLP-1 agonists including albiglutide, and DPP-4 inhibitors compared to other ADAs (reference group). A separate Cox Proportional Hazards model will be run for which the censoring criterion of discontinuation of the index medication is not applied. This model represents an “ever exposed” analysis compared to the “on treatment” analysis above. Secondary analyses will be conducted to determine if there is a relationship between the duration of exposure to albiglutide and acute pancreatitis, using number of prescriptions and cumulative duration of use.

Documents

Study results

gsk-201804-clinical-study-report-redact.pdf(726.28 KB)

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 sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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