Programme of Epidemiological Studies of Lixisenatide and other GLP-1 Receptor Agonists

First published: 05/07/2017

Last updated: 25/06/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS19769

Study ID

19786

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Italy

Study description

I. Database study of GLP-1 Receptor Agonists and Risk of Acute Pancreatitis, Pancreatic Cancer and Thyroid Cancer, in Particular Medullary Thyroid Cancer. This is a retrospective cohort study designed to assess the risk of acute pancreatitis, pancreatic cancer and medullary thyroid cancer associated with use of GLP-1 RA when compared to patients prescribed other types of anti-diabetic drugs. This study will establish the profile of users of GLP-1 RAs and of other anti-diabetic medications. Two cohorts based on prescription databases were established, in Belgium and the Lombardy Region, Italy. Study specific analysis were planned, followed by meta-analyses of the two results.
II. Patient Registry of Lixisenatide Use in Adult Type 2 Diabetes This is a patient registry of patients with diabetes exposed to lixisenatide.
The primary objectives of this study are to monitor the occurrences of acute pancreatitis, pancreatic cancer and thyroid cancer, especially medullary carcinoma of the thyroid, among adult type 2 diabetes patients treated with lixisenatide and to compare their risks with that of users of (1) Other GLP-1 receptor agonists from the Database Study, (2) Other diabetic medications from the Database Study, (3) The general population.

Study status

Ongoing

Research institutions and networks

Institutions

International Prevention Research Institute (IPRI)

France

First published: 19/03/2010

Last updated: 05/04/2012

Institution | EU Institution/Body/Agency | ENCePP partner

AIM-IMA Brussels, Belgium

CRS-SISS Milano, Italy

Contact details

Study institution contact

Peter Boyle Contact-US@sanofi.com

Study contact

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Primary lead investigator

Peter Boyle

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/09/2012

Study start date

Actual: 01/01/2002

Data analysis start date
Actual: 01/07/2015

Date of interim report, if expected
Actual: 12/06/2016

Date of final study report
Planned: 23/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

lixisenatide-epidemiologic-study-protocol-2013-12-02-final.pdf(2.46 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objectives of this study are to estimate:

1. Incidence rates of acute pancreatitis (ICD10 K85) among adult type 2 diabetes patients treated with GLP-1 receptor agonists (i.e. exenatide and liraglutide), as well as patients treated with other anti-diabetic drugs and to examine the risk of acute pancreatitis in users of GLP-1 receptor agonists compared to users of other anti-diabetic medications;
2. Incidence rates of pancreatic cancer (ICD10 C25) among adult type 2 diabetes patients treated with GLP-1 receptor agonists (i.e. exenatide and liraglutide), as well as patients treated with other anti-diabetic drugs and to examine the risk of pancreatic cancer in users of GLP-1 receptor agonists compared to users of other anti-diabetic medications;
3. Incidence rates of thyroid cancer (ICD10 C73) (especially medullary thyroid cancer) among adult type 2 diabetes patients treated with GLP-1 receptor agonists (i.e. exenatide and liraglutide), as well as patients treated with other anti-diabetic drugs and to examine the odds ratio of medullary thyroid cancer in

users of GLP-1 receptor agonists compared to users of other anti-diabetic medications.
This study is designed to focus on the risk associated with use of GLP-1 agonists and will investigate the following primary hypotheses:
1. That adult patients prescribed GLP-1 RAs have an increased risk of acute pancreatitis when compared to patients prescribed other types of anti-diabetic drugs;
2. That adult patients prescribed GLP-1 RAs have an increased risk of pancreatic cancer when compared to patients prescribed other types of anti-diabetic drugs;
3. That adult patients prescribed GLP-1 RAs have an increased risk of medullary thyroid cancer when compared to patients prescribed other types of anti-diabetic drugs.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Name of medicine

LYXUMIA

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

LIXISENATIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ03) lixisenatide

lixisenatide

Medical condition to be studied

Pancreatitis

Pancreatic carcinoma

Medullary thyroid cancer

Population studied

Short description of the study population

The study focused on diabetic patients prescribed with lixisenatide identified from the patients registry in Denmark, Norway and Sweden.

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

Diabetic patients

Estimated number of subjects

550000

Study design details

Outcomes

Acute pancreatitis, pancreatic cancer, medullary thyroid cancer.

Data analysis plan

The studies in Belgium and Lombardy Region are based on the same protocol using the same methods for subject selection, drug exposure assessment, and statistical analysis. In both settings a “new users design” is implemented.Subjects contribute in a time dependent manner to the different exposure groups.Crude and standardized incidence rates (per 100,000 person years) of the outcome event are calculated for each exposure group. The risk of outcome events is evaluated using Cox proportional hazard models including time-dependent variables, stratified on age and gender and adjusted for gallbladder disease and insulin therapy. Hazard ratios (HRs) from Belgium and Italy are pooled using fixed effects meta-analyses.

Documents

Study results

csr-lixisenatide-PASS-EMA.pdf(2.64 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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