Incretin-based therapies and Pancreatic Cancer risk in Medicare enrollees – new user protocol

First published: 21/12/2012

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/8912

EU PAS number

EUPAS3255

Study ID

8912

DARWIN EU® study

No

Study countries

☐ United States

Study description

This will be a retrospective cohort study using a new-user active comparator design on Medicare Part A, B and D claims data from 2006-2010. The study population consists of Medicare enrollees initiating Incretin-based drugs (IBRx) or other antidiabetic drugs (CompRx). Newusers of IBRx and CompRx will be compared with respect to incidence of pancreatic cancer (primary outcome) and incidence of mortality due to pancreatic cancer (secondary outcome) adjusted for baseline information collected prior to drug initiation. Given the FDA signal about increased pancreatic cancer reporting with IBRx, it is possible that IBRx new-users are subjected to increased screening and there is increased/earlier detection of pancreatic cancer in the IBRx group compared to the CompRx group. We will therefore evaluate and quantify the use of diagnostic procedures that may lead to a preclinical diagnosis of pancreatic cancer among new users of IBRx and CompRx in the 6 month period before and after the start of drug therapy.

Study status

Finalised

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department of Epidemiology

Contact details

Study institution contact

Til Stürmer

Study contact

sturmer@unc.edu

Primary lead investigator

Til Stürmer

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/08/2012

Study start date

Planned: 24/12/2012

Actual: 24/12/2012

Data analysis start date

Planned: 24/12/2012

Actual: 24/12/2012

Date of final study report

Planned: 20/12/2013

Actual: 10/09/2014

Sources of funding

- Other

More details on funding

University of North Carolina Chapel Hill Clinical and Translational Science Awards (UNC-CTSA)

Study protocol

Incretin_PC_protocol 20DEC2012.pdf(246.52 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Other

Study topic, other:

Diagnostic procedures

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:

The primary objective of this study is to examine the effect of initiation of incretin-based therapies (IBRx) relative to other anti-diabetic therapies (CompRx) on the incidence of pancreatic cancer based on a new-user active comparator design. A secondary aim is to evaluate the use of diagnostic procedures that may lead to a preclinical diagnosis of pancreatic cancer prior to and after initiation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

BYDUREON

BYETTA

JANUVIA

ONGLYZA

VICTOZA

Medical condition to be studied

Diabetes mellitus

Population studied

Short description of the study population

Medicare enrollees > 65 years of age initiating Incretin-based drugs (IBRx) or other antidiabetic drugs (CompRx)

Age groups

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

Diabetes mellitus patients

Estimated number of subjects

75000

Study design details

Outcomes

Incident pancreatic cancer, pancreatic cancer mortality, incidence of diagnostic work-up

Data analysis plan

IBRx new-users will be compared with new users of CompRx with respect to incidence of pancreatic cancer diagnosis, pancreatic cancer mortality and incidence of diagnostic work-up. We will use propensity scores to balance measured risk factors for cancer/diagnostic work-up between these cohorts. Hazard rates for each of the outcomes will be estimated using a Cox proportional hazards model controlling for age and sex as well as any covariates remaining imbalanced after implementation of the propensity score. In addition, cumulative incidence of diagnostic work-up in the IBRx and CompRx groups across time before and after drug initiation will be examined. Please see full protocol for additional details and description of secondary and sensitivity analyses.

Documents

Study results

Summary of results_incretin manuscript.pdf(304.27 KB)

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