Incretin-based drugs and Retinopathy risk in Medicare Enrollees

First published: 09/02/2017

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/17777

EU PAS number

EUPAS17776

Study ID

17777

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 2006-2014. The study population consists of Medicare enrollees initiating incretin-based drugs (GLP-1 receptor agonists or DPP-4 inhibitors) or other antidiabetic drugs (thiazolidinediones, sulfonylureas or long-acting insulins). New users of incretin-based drugs and other antidiabetic drugs will be compared with respect to the incidence of retinopathy, adjusted for baseline information collected prior to drug initiation.

Study status

Ongoing

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

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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

Planned: 09/02/2017

Actual: 09/02/2017

Study start date

Planned: 09/02/2017

Actual: 09/02/2017

Data analysis start date

Planned: 09/02/2017

Actual: 09/02/2017

Date of final study report

Planned: 28/02/2018

Sources of funding

- Other

More details on funding

Unfunded

Study protocol

RetinopathyProtocol 08FEB2017.pdf(883.98 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To examine the effect of initiation of incretin-based therapies (IBRx) relative to other antidiabetic therapies (CompRx) on the incidence of retinopathy based on an active comparator new-user study design.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10) DRUGS USED IN DIABETES

DRUGS USED IN DIABETES

Medical condition to be studied

Retinopathy

Diabetes mellitus

Population studied

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

350000

Study design details

Outcomes

Incident Retinopathy

Data analysis plan

IBRx new-users will be compared with new users of CompRx with respect to incidence of retinopathy diagnosis. We will use propensity scores to balance measured risk factors for retinopathy between these cohorts. Hazard rates for retinopathy 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.

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