Alogliptin-5002: Association between therapy with Dipeptidyl peptidase-4 (DPP-4) inhibitors and risk of ileus: A cohort study

First published: 06/05/2015

Last updated: 16/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44018

EU PAS number

EUPAS8734

Study ID

44018

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Ileus is a form of non-mechanical bowel obstruction. A recent literature report of three cases of ileus in DPP-4 inhibitors treated patients in Japan has triggered this epidemiology study to quantify and assess the risk. To quantify the incidence rate of ileus among T2DM patients new users of alogliptin, other DPP-4 inhibitors, Glucagon-Like Polypeptide-1 (GLP-1) receptor agonists and Voglibose. This is a retrospective cohort study using a Japanese Medical Data Vision (MDV) claims database. The study population includes T2DM patients who were new users of alogliptin, other DPP-4 inhibitors, GLP-1 receptor agonists, or Voglibose between 04/01/2010-04/30/2014. New users defined as patients without any previous prescriptions for medications of interest before cohort entry. Patients were aged 40+ years at cohort entry and were followed up until the earliest of: incident diagnosis of ileus, or the earliest of the last prescription date of the first therapy episode or day before date of treatment switch/add-on. Incidence rates of ileus were assessed, both overall and by risk time window. Poisson regression models assessed incidence rate ratios (IRR) for ileus with 95% confidence intervals (95% CI).

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

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Primary lead investigator

Dimitri Bennett

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/12/2014

Actual: 23/12/2014

Study start date

Planned: 30/01/2015

Actual: 30/01/2015

Data analysis start date

Planned: 01/02/2015

Actual: 01/02/2015

Date of final study report

Planned: 31/07/2015

Actual: 09/07/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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

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:

We will use the MDV database in Japan to conduct a retrospective cohort study among T2DM patients who received a prescription for alogliptin, another DPP-4 inhibitor, a GLP-1 receptor agonist, or voglibose between April 1, 2010 and April 30, 2014 (study enrolment period).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ALOGLIPTIN

Medical condition to be studied

Ileus

Diabetes mellitus

Population studied

Short description of the study population

Patients with T2DM who were new users of alogliptin, another DPP-4 inhibitor, a GLP-1 receptor agonist, or voglibose between April 1, 2010 and April 30, 2014 were selected. New users were defined as adults 40 years of age or older at cohort entry date and having at least one year of enrollment in the MDV database without any previous prescriptions for alogliptin, other DPP-4 inhibitors, GLP-1 receptor agonists, or voglibose. Participants with a record of an ileus diagnosis in the year before or on the cohort entry date were excluded to avoid misclassification of prevalent ileus cases as incident cases.

Age groups

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 with ileus

Estimated number of subjects

234089

Study design details

Outcomes

The primary outcome in our study will be an incident diagnosis of ileus (identified by the ICD-10 codes of K56.7 for Ileus, unspecified and K56.0 for paralytic ileus) occurring after the cohort entry date (CED).

Data analysis plan

Descriptive statistics, including means (SD) and medians (10th to 90th percentiles) for continuous variables, and numbers and percentages for categorical variables will be used to examine patient baseline characteristics in the cohorts of interest, and the presence of ileus. Incidence rates of ileus per 1000 person-years with 95% confidence intervals (CIs) for the study and comparators cohort will be calculated. In addition, the incidence rates of ileus will be stratified by the following risk window time frames from the date of first prescription

Documents

Study results

Alogliptin-5002-RDS-2015-07-09.pdf(151.38 KB)

Data management

Data sources

Data source(s), other

Medical Data Vision Co Ltd Japan

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