Risk of lactic acidosis with metformin use in type 2 diabetes mellitus with renal impairment: retrospective cohort study

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/18820

EU PAS number

EUPAS8658

Study ID

18820

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study will be conducted using the Clinical Practice Research Datalink (CPRD). The CPRD is the English NHS observational data and interventional research service and will be the primary data source for patients in the United Kingdom.This is a retrospective cohort study in observational data. Eligible patients are those diagnosed with Type 2 Diabetes Mellitus (T2DM) with or without therapy. Patients will be included if: 1) had at least one measure of Glomerular Filtration Rate (GFR) between 2007-2012 or their chronic kidney disease (CKD) measured, 2) regardless of T2DM diagnoses date, 3) with or without therapy, 4) regardless of whether they were using insulin concomitant to other OAD drugs, and 5) have at least 1 follow-up during the study period. Patients will be excluded if: 1) they are exclusively type I diabetes insulin.

Study status

Finalised

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

Communication Center Merck KGaA

Study contact

service@merckgroup.com

Primary lead investigator

Responsible Medical

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/06/2013

Study start date

Actual: 15/07/2013

Date of final study report

Actual: 17/10/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck KGaA

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:

To estimate the incidence of lactic acidosis associated with metformin use in patients with moderate renal impairment (GFR 30-59ml/min) compared to

patients with a GFR >60 ml/min.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

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

METFORMIN

Medical condition to be studied

Diabetes mellitus

Renal impairment

Population studied

Short description of the study population

Patients who were diagnosed with Type 2 Diabetes Mellitus (T2DM) with or without therapy. Patients were be included if: 1) had at least one measure of Glomerular Filtration Rate (GFR) between 2007-2012 or their chronic kidney disease (CKD) measured; 2) regardless of T2DM diagnoses date, 3) with or without therapy, 4) regardless of whether they were using insulin concomitant

to other OAD drugs, and 5) have at least 1 follow-up during the study period.

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

Renal impaired

Estimated number of subjects

135000

Study design details

Data analysis plan

Data analysis will consist of incidence rates in 100,000 person-years of lactic acidosis in patients with T2DM using metformin and having different CKD staging. A secondary analysis of the incidence of LA in patients using Metformin versus those using other antidiabetic drugs by stages of CKD will be performed. Lactic acidosis includes both cases of fatal and cases of non-fatal lactic acidosis. Upper and lower limits of 95% confidence intervals will be given.

Data management

Data sources

Data source(s)

Clinical Practice Research Datalink

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