Metformin use in renal impairment

First published: 26/11/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40847

EU PAS number

EUPAS5249

Study ID

40847

DARWIN EU® study

No

Study countries

☐ Denmark

☐ United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital
DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

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Institution **Educational Institution** **ENCePP partner**

Boston Collaborative Drug Surveillance Program

Boston, USA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/07/2013

Actual: 31/07/2013

Study start date
Planned: 16/12/2013

Actual: 16/12/2013

Data analysis start date
Planned: 16/12/2013

Actual: 16/12/2013

Date of interim report, if expected
Planned: 31/03/2014

Actual: 30/04/2014

Date of final study report
Planned: 30/06/2014

Actual: 30/06/2014

Sources of funding

- EMA

Study protocol

Metformin use in renal impairment Final Protocol 2013-10-31.pdf(1.12 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1. To conduct a systematic review of literature relevant to metformin use and renal impairment2. To examine a.prevalence of renal impairment and other

characteristics among new and prevalent users of metformin, b) use of metformin in patients with type 2 diabetes according to stage of renal function impairment c) Safety of metformin regarding renal impairment and lactic acidosis

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

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

METFORMIN

Medical condition to be studied

Renal impairment

Lactic acidosis

Population studied

Short description of the study population

The source population for the study will be male and female residents of Denmark and United Kingdom (UK) – the two EU member states covered by relevant medical databases. The study population will consist of patients with medically treated type 2 diabetes, defined as persons with at least one

prescription for an antidiabetic medication aged 30 years or older at time of first recorded prescription. The study population was restricted to patients aged 30 years or older to exclude people with polycystic ovary syndrome and type 1 diabetes, which both are frequently diagnosed under age 30. Only patients with at least one year of prescription history before the index date (study entry or start of follow-up) will be included in order to have an observable washout period for identification of new users. In addition, we will require patients to have at least one measurement of creatinine before study inclusion in order to assess baseline renal function. In Denmark, the study population will be restricted to residents of the North and the Central Denmark regions covered by the Aarhus University Research Database, which includes information on filled prescriptions and laboratory data. In the United Kingdom, the study population will be restricted to patients treated by general practitioners participating in the Clinical Practice Research Datalink (CPRD) and who meet the study criteria.

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

Renal impaired

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

22000

Study design details

Outcomes

lactic acidosisrenal impairment

Data analysis plan

-- Drug utilisation study - cross tabulation of distributions and patient characteristics-- incidence and prevalence of primary outcomes-- analysis of risk factors for lactic acidosis

Documents

Study results

Metformin use in renal impairment FINAL REPORT 30june2014_executive summary uploaded to ENCePP.pdf(128.63 KB)

Study, other information

Metformin use in renal impairment Final Protocol 2013-10-31 Data sharing statement.pdf(89.59 KB)

Study publications

Li L, Jick S, Gopalakrishnan C, Heide-Jørgensen U, Nørrelund H, Sørensen HT, Ch…

Christiansen CF, Ehrenstein V, Heide-Jørgensen U, Skovbo S, Nørrelund H, Sørens…

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

CoI.pdf(86.61 KB)

Composition of steering group and observers

Steering group statement (metformin).pdf(96.28 KB)

Signed code of conduct

2013-0023_CoC Declaration-SDPP-5249.pdf(67.96 KB)

Signed code of conduct checklist

2013-0023-CoC Checklist-SDPP-5249.pdf(284.73 KB)

Signed checklist for study protocols

2013-0023-Checklist for study protocol-SDPP-5249.pdf(373.02 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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