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 institution and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
First published: 20/07/2021
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02/04/2024

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 data collection

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 data (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