Impact of risk minimisation in patients treated with rosiglitazone-containing products

First published: 26/01/2011

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1777

Study ID

40844

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ United Kingdom

Study description

This study will examine the effects of regulatory risk-minimisation measures on utilization of rosiglitazone containing products in the population, on incidence of acute drug reactions and on potential changes in objective diseases parameters in individual patients.

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**

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

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Institution | Educational Institution | ENCePP partner

Boston Collaborative Drug Surveillance Program (GPRD access) Boston, USA

Contact details

Study institution contact

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Primary lead investigator

Henrik Toft Sørensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/12/2010

Study start date

Planned: 01/02/2011

Actual: 01/02/2011

Data analysis start date
Planned: 01/02/2011

Actual: 01/02/2011

Date of interim report, if expected
Planned: 01/04/2011

Actual: 01/05/2011

Date of final study report
Planned: 01/10/2011

Actual: 17/10/2011

Sources of funding

- EMA

Study protocol

Protocol_ENcEPP_Submitted.pdf (200.49 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe trends in patterns of utilisation of rosiglitazone-containing preparations over time in response to risk minimsation events (switches to and from rosiglitazone-containing preparations),To examine prevalence of ontraindicated and offlabel use,To examine risk of acute drug reactions after risk minimisationTo examine changes in objective parameters of disease in medication switchers

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BD03) metformin and rosiglitazone

metformin and rosiglitazone

(A10BD04) glimepiride and rosiglitazone

glimepiride and rosiglitazone

(A10BG02) rosiglitazone

rosiglitazone

Population studied

Short description of the study population

The study population will include, in both countries, diabetic patients treated with oral glucose lowering drugs between 1 January 2000 and 1 January 2011. This period covers the time from the approval of rosiglitazone for use in the European Union, in July 2000, until the decision by the European Medicines Agency to suspend the drug, on 23 September 2010. The study period also includes a pre-approval and a post-suspension periods to allow examination of drug utilization

patterns in response to these events.

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)

Estimated number of subjects

20000

Study design details

Data analysis plan

1.Descriptive drug utlization patterns according to calendar time2. Prevalences of off-label and contraindicated use3. Incidence rates and rate ratios of acute drug reactions according to patterns of oral antidiabetic use4. Changes in laboratory parameters of disease comparing values before and after medication switch/regulatory decisions5. Risk of lab-based disease events

Documents

Study results

Rosiglitazone_executive_summary_for_ENCePP.pdf (12.41 KB)

Study, other information

Data access procedures.pdf (10.31 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Conflict of interest statement.pdf (7.44 KB)

Composition of steering group and observers

Steering Committee statement.pdf (7.44 KB)

Signed code of conduct

2011-0004-cocdecl 14.01.2011.pdf (32.03 KB)

Signed code of conduct checklist

2011-0004-CoCcklist 21.01.1011.pdf (183.17 KB)

Signed checklist for study protocols

2011-0004-cklistmeth14.01.2011.pdf (165.32 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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