Monitoring the effectiveness of risk minimisation in patients treated with pioglitazone-containing products

First published: 12/07/2012

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16740

EU PAS number

EUPAS2765

Study ID

16740

DARWIN EU® study

No

Study countries

☐ Denmark

☐ Netherlands

☐ United States

Study description

The study has the following objectives 1: To provide observational data on drug utilisation patterns of pioglitazone-containing products in the European Union (EU) and to study associations between changes in drug utilisation patterns and the regulatory decisions in the form of DHPC. 2a: To analyse events in patients discontinuing pioglitazone after the DHPC, including adverse drug events, alterations in glycaemic control, and modification of other objective parameters of disease.2b: To analyse contraindications and events in patients continuing or starting pioglitazone, including adverse drug events, alterations in glycaemic control, and modification of other objective parameters of disease.3. To evaluate effectiveness of risk minimisation measures recommended by CHMP based on results obtained for Objective 1 and Objective 2.4. To provide practical recommendations for improving effectiveness of risk minimisation measures.The objectives of the study will be achieved using data from automated pharmacoepidemiologic databases in three EU Member states: Denmark, The Netherlands, and 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

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Boston Collaborative Drug Surveillance Program

Boston, USA

Networks

EU-ADR Alliance

First published: 01/02/2024

Last updated: 01/02/2024

Network

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: 20/01/2012

Actual: 20/01/2012

Study start date
Planned: 06/08/2012

Actual: 14/08/2012

Data analysis start date
Planned: 03/09/2012

Actual: 03/09/2012

Date of interim report, if expected
Planned: 20/11/2012

Actual: 29/11/2012

Date of final study report
Planned: 20/02/2013

Actual: 29/11/2012

Sources of funding

- EMA

Study protocol

D4 b Final Study Protocol vFinal.pdf(414.76 KB)

D4 b Final Study Protocol vFinal_Amendment 07 11 2012.pdf(385.66 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:

 Objective 1: To provide observational data on drug utilisation patterns of pioglitazone-containing products in the European Union (EU) and to study

associations between changes in drug utilisation patterns and the regulatory decisions in the form of DHPC. Objective 2a: To analyse events in patients discontinuing pioglitazone after the DHPC, including adverse drug events

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BD05) metformin and pioglitazone

metformin and pioglitazone

(A10BD09) pioglitazone and alogliptin

pioglitazone and alogliptin

(A10BG03) pioglitazone

pioglitazone

Population studied

Short description of the study population

Patients treated with pioglitazone-containing products from Denmark, Netherlands and UK.

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

10000

Study design details

Outcomes

changes in drug utilizatonchanges in objective parameters of disease in response to labeling change

Data analysis plan

Changes of drug utilization patterns overall and in patient groupsChanges of objective disease parameters in patients continuing and stopping containing products

Documents

Study results

D5.a Interim report on the study results.pdf(770.06 KB)

D5b D1 D2 Final report on study results_final version.pdf(799.42 KB)

Study report

D5.a Interim report on the study results (Appendix 2).pdf(410.29 KB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

2012-0010-DoI HT Sorensen-SDPP-2765.pdf(120.98 KB)

Composition of steering group and observers

Steering Committee_Pioglitazone.pdf(6.51 KB)

Signed code of conduct

2012-0010-DoC CoC-SDPP-2765.pdf(28.62 KB)

Signed code of conduct checklist

2012-0010-Checklist CoC-SDPP-2765.pdf(221.31 KB)

Signed checklist for study protocols

2012-0010-Checklist Study Protocol-SDPP-2765.pdf(159.52 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

Integrated Primary Care Information (IPCI)

Data source(s), other

CPRD, Danish Registries (access/analysis), IPCI

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, 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

Unknown