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

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#### 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** 

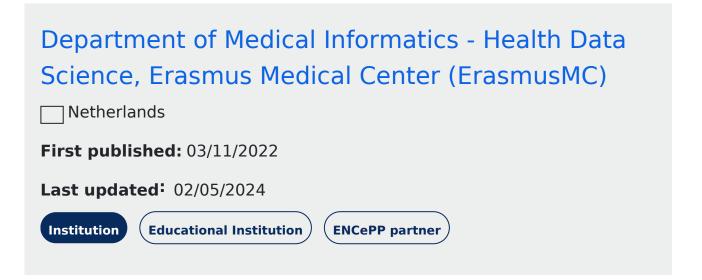
# Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY Denmark First published: 20/07/2021 Last updated: 02/04/2024

**ENCePP** partner

**Educational Institution** 

Institution





### Boston Collaborative Drug Surveillance Program Boston, USA

#### **Networks**

#### **EU-ADR Alliance**

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Network

#### Contact details

**Study institution contact** 

Vera Ehrenstein

Study contact

ve@dce.au.dk

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

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

Was the study required by a regulatory body?

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-Dol 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