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

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# Administrative details

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

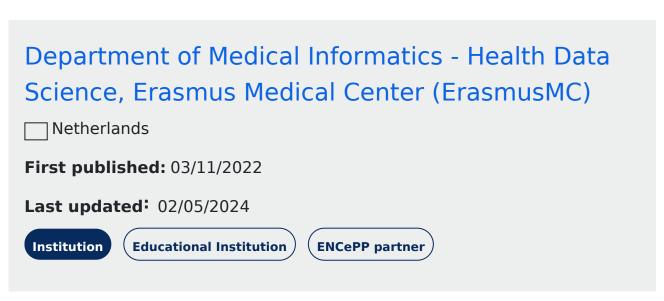
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Institution Educational Institution ENCePP partner





Boston Collaborative Drug Surveillance Program Boston, USA

#### **Networks**

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

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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

# Data collection methods:

Secondary use of data

Drug utilisation

#### 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**

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**

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