# 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.

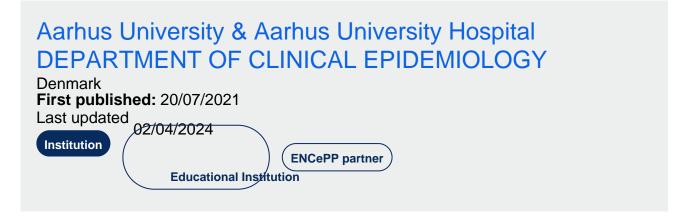
#### Study status

Finalised

## Research institution and networks

## Institutions





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

Netherlands



# 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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**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 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 data collection

#### Main study objective:

? Objective 1: To provide observational data on drug utilisation patterns of pioglitazonecontaining 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 (A10BD09) pioglitazone and alogliptin (A10BG03) 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

#### 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) 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