A PHARMO Study on the Utilization of Pioglitazone in Clinical Practice in The Netherlands with Regard to Diabetic Treatment Regimen and Co-morbidities

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Study Finalised

Administrative details

EU PAS number

EUPAS10001

Study ID

28851

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

The goal of this study is to describe the prescription of pioglitazone in diabetic patients according to Summary of Product Characteristics (SmPC), and to evaluate the implementation of the risk minimization measures introduced in July 2011 regarding bladder cancer and heart failure and the need for regular review of the benefits of therapy. This drug utilization study will describe the pioglitazone users with regard to age, sex, concomitant drug use, and prevalent comorbidities at the time of their first pioglitazone prescription, specifically hypertension and ischemic heart disease.

Study status

Finalised

Research institutions and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

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Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ron Herings

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 23/07/2012

Study start date
Actual: 01/08/2012

Data analysis start date
Actual: 01/09/2012

Date of final study report
Actual: 17/10/2012

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TDC Europe

Study protocol

PHARMO_Protocol_Pioglitazone_DUS.pdf (245.46 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the utilization patterns of pioglitazone for the period up to and including August 31st, 2007, between September 1st, 2007 and September 30th, 2010, between October 1st, 2010 and July 31st, 2011, and after July 31st, 2011.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ACTOS

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

All diabetic patients in the PHARMO database who ever received ≥1 prescription for pioglitazone, alone or in a combination therapy with metformin,

a sulfonylurea drug, other oral antidiabetic drugs, or insulin, between June 1999 and May 2012 for the analysis relating to objectives 1 and 2 (heart failure and comedication with insulin).

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)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

2238

Study design details

Outcomes

To estimate the incidence and prevalence of heart failure in diabetic patients prescribed pioglitazone, both overall and stratified by insulin co-medication status. To describe the patients who were given pioglitazone despite the contraindications given on its label.

Data analysis plan

The key demographics will be presented before and after each major change to theproduct information or other factors potentially affecting pioglitazone use (31 August 2007, September 2010, July 2011). The overall analysis will be performed using data from the entire study period, the stratified analysis will use data up to a change in concomitant insulin treatment: patients will be stratified based on index use of concomitant insulin use and will no longer be followed after a change in insulin treatment.

Documents

Study results

AD-4833-409B-RDS-2012-10-17.pdf (16.7 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.

Data sources

Data source(s)

PHARMO Data Network

Data sources (types)

Electronic healthcare records (EHR)

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