A Study on the Utilization of Pioglitazone in Clinical Practice With Regard to Diabetic Treatment Regimen and Comorbidities

First published: 21/07/2015

Last updated: 16/08/2016

Study Finalised

Administrative details

EU PAS number

EUPAS9998

Study ID

14800

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The goal of this study is to describe the prescription of pioglitazone in diabetic patients according to Summary of Product Characteristics, and to evaluate the implementation of the risk minimisation measures introduced in July 2011 regarding bladder cancer, 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 ischaemic heart disease.

Study status

Finalised

Research institutions and networks

Institutions

University Hospital of Basel

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Christoph Meier

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 15/06/2012

Study start date
Actual: 01/07/2012

Data analysis start date
Actual: 01/08/2012

Date of final study report
Actual: 30/04/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TDC Europe

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The goal of this study is to describe the prescription of pioglitazone in diabetic patients according to Summary of Product Characteristics, and to evaluate the

implementation of the risk minimisation measures introduced in July 2011 regarding bladder cancer, heart failure, and the need for regular review of the benefits of therapy.

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

Patients with pioglitazone use where most patients were between 50 and 79 years of age having type 2 diabetes mellitus along with comorbidities like hypertension and ischaemic heart disease.

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

32.947

Study design details

Outcomes

To describe trends in pioglitazone prescription patterns over time, before and after the key risk minimization milestones, To estimate the prevalence and incidence of HF in diabetic patients using pioglitazone, overall and stratified by insulin co-medication.

Data analysis plan

For all patients who ever received >= 1 prescription for pioglitazone, we will assess their age at first use, gender, body mass index, smoking status and the year in which the pioglitazone treatment was started, as well as concomitant drug use in the 12 months prior to starting pioglitazone, concomitant drug use after starting pioglitazone, and comorbidities at treatment initiation based on the entire available recorded patient history prior to starting pioglitazone.

Documents

Study results

AD-4833-409A-RDS-2013-04-02.pdf (75.55 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)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Clinical Practice Research Datalink (CPRD) GOLD is the UK primary care database.

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

No