Assessment of Utilisation of Pioglitazone in Denmark Post Label Change (July 2011)

First published: 21/07/2015

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8408

Study ID

19830

DARWIN EU® study

No

Study countries

Denmark

Study description

On the 11 of July 2011, EMA approved a label change for Pioglitazone that included new labelling on haematuria, bladder cancer and guidance on monitoring treatment effectiveness. A Dear Healthcare Provider Communication

(DHPC) letter was sent to Danish prescribers on 11 August 2011 informing them of the label change. This drug utilisation study (DUS) aims to assess compliance with prescribing information in Denmark following the July 2011 labelling changes.

Study status

Finalised

Research institutions and networks

Institutions

PPD Evidera

Sweden

United Kingdom

United States

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Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Primary lead investigator

Javier Cid

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/02/2015

Actual: 06/02/2015

Study start date

Planned: 01/07/2015

Actual: 08/11/2015

Data analysis start date

Planned: 01/03/2016

Actual: 01/03/2016

Date of final study report

Planned: 29/07/2016

Actual: 27/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda 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

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

This drug utilisation study (DUS) aims to assess compliance with prescribing information in Denmark following the July 2011 labelling changes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ACTOS

Population studied

Short description of the study population

Pioglitazone users in Denmark between 11 August 2011 and 15 November 2013.

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

Type 2 diabetes mellitus patients

Estimated number of subjects

100

Study design details

Outcomes

To quantify the number of incident and prevalent users of pioglitazone in Denmark after the DHPC letter on11 August 2011, including duration of use among incident users. To describe patterns of antidiabetic co-medication use among incident and prevalentpioglitazone users after the DHPC letter on 11 August 2011.

Data analysis plan

There will be four separate study populations.1. Incident pioglitazone users: all patients with ≥ one new prescription (first-time prescription only, or first-time prescription and following prescriptions) for pioglitazone between 11 August 2011 and 31 December 2014, who have not had any pioglitazone prescription recorded in the 12 months prior to 11 August 2011. Patients are eligible if they have at least 12 months of data recorded prior to the index date for incident users, i.e. date of the first-time pioglitazone prescription.2. Prevalent pioglitazone users: all patients with ≥ one prescription for pioglitazone between 11 August 2011 and 31 December 2014, who also had ≥ one pioglitazone

prescription recorded prior to 11 August 2011. Patients are eligible if they have at least 12 months of data recorded prior to index date for prevalent users, i.e. prior to 11 August 2011.

Documents

Study results

Study_report_abstract.pdf (46.61 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)

Danish registries (access/analysis)

Data sources (types)

Disease registry

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