A study on the utilization of pioglitazone in clinical practice in the UK after the label change in July 2011

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Study Finalised

Administrative details

EU PAS number

EUPAS9995

Study ID

14797

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This study aims to describe the prescription pattern of pioglitazone in diabetic patients within the UK after the label change in July 2011 and measure the effectiveness of the additional risk minimization activities related to pioglitazone, as there have been safety concerns for pioglitazone regarding bladder cancer, heart failure (HF), and off label use as first-line therapy. Data will be obtained from the UK based Clinical Practice Research Datalink (CPRD) during a study period between 21 July 2011 and the end of December 2013. Cumulative incidence rates (CIRs) of HF in incident and prevalent pioglitazone users will be calculated separately, stratified according to whether or not insulin was co-prescribed. Study will further assess prescription patterns regarding the previously implemented risk minimization measures for pioglitazone, i.e. the proportion of stopped therapy following an incident diagnosis for bladder cancer, macroscopic hematuria, or an unacceptably high HbA1c level in incident and prevalent pioglitazone users separately.

Study status

Finalised

Research institutions and networks

Institutions

Basel Pharmacoepidemiology Unit, University 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: 26/05/2014

Study start date

Actual: 01/06/2014

Data analysis start date

Actual: 01/07/2014

Date of final study report

Actual: 31/07/2014

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:

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:

The overall aim of this DUS was to assess the effectiveness of the July 2011 labeling update for pioglitazone in clinical practice within the UK.

Study drug and medical condition

Name of medicine

PIOGLITAZONE

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Prescription pattern of pioglitazone was evaluated in diabetic patients within the UK after the label change in July 2011.

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

14794

Study design details

Outcomes

To quantify the number of incident and prevalent users of pioglitazone in the UK after the label change on 21 July 2011. Duration of T2DM before treatment start with pioglitazone, Prevalent comorbidities and contraindications, Exposure duration to Pioglitazone

Data analysis plan

We will establish 3 different models to assess the prescription pattern of pioglitazone,to learn more about drug utilization of incident and prevalent pioglitazone users after 21 July 2011. We will assess T2DM disease duration prior to treatment initiation with pioglitazone in incident users. Among incident pioglitazone users after 21 July 2011, we will quantify the proportion of patients with a history (i.e. a prevalent diagnosis) of hypertension, ischemic heart disease, myocardial infarction, chronic kidney disease (CKD, incl. dialysis), and chronic obstructive pulmonary disease (COPD) at the time of the first pioglitazone prescription, based on the entire available recorded patient history prior to starting pioglitazone.

Documents

Study results

AD-4833-411-RDS-2014-08-01.pdf(80.21 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)

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