Exposure to pioglitazone and the risk of prostate cancer: a nested case-control study

First published: 13/04/2016

Last updated: 25/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11750

Study ID

48533

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Several previous epidemiological studies have investigated pioglitazone and risk of prostate cancer with conflicting results. This study aims to use CPRD GOLD to further investigate if there is an association between pioglitazone use and the development of prostate cancer, and to explore the possible reasons for such an association and whether this is unique to pioglitazone or seen also with other diabetic treatments. This nested case-control study will be set within a CPRD GOLD cohort of male type 2 diabetes mellitus (T2DM) patients, aged 40 years or over, who initiated first ever diabetic drug therapy on or after 01 January 2001 until the most recent date of the three databases. Cases of prostate cancer diagnosed after the start of first diabetic medication will be identified using linkage to Cancer Registration data, and hospital discharge diagnoses in the HES dataset. This observational study will estimate risk of prostate cancer in relation to ever having been exposed to pioglitazone and also with duration and cumulative dose of pioglitazone exposure. Conditional logistic regression analyses will be used to generate risk estimates while adjusting for potential confounding factors.

Study status

Finalised

Research institutions and networks

Institutions

ICON Commercialisation & Outcomes

Germany

Ireland

First published: 19/03/2010

Last updated: 05/07/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 2 centres are involved in the study

Contact details

Study institution contact

Naomi Boxall trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Naomi Boxall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/04/2015

Actual: 16/04/2015

Study start date
Planned: 15/01/2016

Actual: 15/01/2016

Data analysis start date
Planned: 05/02/2016

Actual: 05/02/2016

Date of final study report
Planned: 29/07/2016

Actual: 11/07/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to investigate if there is an association between pioglitazone use and the risk of prostate cancer.

Study Design

Non-interventional study design

Case-control

Other

Non-interventional study design, other

Nested, matched case-control study

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Prostate cancer

Population studied

Short description of the study population

Patients aged 40 years or older with type II diabetes mellitus and matched controls with prostate cancer identified from the Clinical Practice Research Datalink (CPRD) between 01 January 2001 and 05 January 2015.

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

55.000

Study design details

Outcomes

Number of Participants Reporting Prostate Cancer Related to Pioglitazone. 1) Duration of Pioglitazone Exposure. 2) Cumulative Dose of Pioglitazone Exposure.

Data analysis plan

Conditional logistic regression will be used to calculate the adjusted Odds Ratios (OR) of prostate cancer associated with use of pioglitazone.

Documents

Study results

Abstract Pioglitazone_5018_Redacted.pdf (615.2 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)

Administrative healthcare records (e.g., claims)

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

No