Association between Pioglitazone and Bladder Cancer in a Medicare population

First published: 26/04/2016

Last updated: 27/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS13279

Study ID

15784

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study utilizes a 20% random sample of Medicare Parts A, B and D claims data from 2006-2013 (2014 data may be added if it becomes available) to conduct an incident user comparative safety retrospective cohort study. The

cohorts will include beneficiaries aged 66 or older with diabetes who initiate pioglitazone, a dipeptidyl-peptidase 4 inhibitors, or a sulfonylureas. Incident users of pioglitazone will be compared with incident users of a dipeptidyl-peptidase 4 inhibitors, or a sulfonylureas with respect to incidence of bladder cancer.

Study status

Planned

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Gillings School of Global Public Health

Contact details

Study institution contact

Til Stürmer sturmer@unc.edu

Study contact

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Primary lead investigator

Til Stürmer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2016

Study start date

Planned: 01/04/2016

Date of final study report

Planned: 31/10/2016

Sources of funding

- Other

More details on funding

Unfunded

Study protocol

PioBladderCancer_SafetyProtocol_ENCePPv25Apr2016.pdf(237.74 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Examine the effect of initiation of pioglitazone relative to dipeptidyl-peptidase 4 inhibitors and/or sulfonylureas on the incidence of bladder cancer based on a new-user active comparator design.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BB) Sulfonylureas

Sulfonylureas

(A10BG03) pioglitazone

pioglitazone

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

150000

Study design details

Outcomes

Incidence of invasive and in situ bladder cancer

Data analysis plan

New users of pioglitazone(PIO) will be compared with new users of dipeptidyl-peptidase 4 inhibitors(DPP) or sulfonylureas(SU) with respect to incidence of

bladder cancer. Propensity score weighting will be used to create pseudo-populations in which all baseline risk factors are balanced between each of the comparison cohorts (PIO vs DPP and PIO vs. SU). The date of dispensing of a second prescription within each exposure group will serve as the cohort entry date and the start of follow-up. The primary ‘as-treated’ analysis, will follow patients until the outcome occurs or the date of first occurrence of death, end of study (31 Dec 2013 2014 data may be added if it becomes available), end of enrollment, or change in therapy (discontinuation, switch, or augment). An additional ‘intention to treat’ analysis will follow patients without regard for change in therapy. See full protocol for additional details and description of secondary and sensitivity analyses.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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