Pioglitazone Use and Risk of Bladder Cancer: a Systematic Review and Meta-Analysis of Observational Studies

First published: 07/11/2016
Last updated: 30/03/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/18799

EU PAS number
EUPAS16082

Study ID
18799

DARWIN EU® study
No

Study countries
Finland

Study description
The primary research question is whether type 2 diabetes mellitus patients treated with pioglitazone are at a higher risk of bladder cancer compared to type 2 diabetes mellitus patients who are not treated with pioglitazone. The secondary research question is whether the risk of bladder cancer is increased by cumulative exposure duration or cumulative dose of pioglitazone.This meta-analysis will be based on a systematic and comprehensive literature review that will be conducted to identify eligible observational studies from peer-reviewed scientific journals.

Study status
Finalised

Research institution and networks

Institutions

EPID Research Oy
First published: 01/02/2024
Last updated 01/02/2024
Institution

Contact details

Study institution contact
Pasi Korhonen
Study contact

pasi.korhonen@epidresearch.com
Primary lead investigator
Pasi Korhonen
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
02/08/2016
Actual:
02/08/2016

Study start date
Planned:
28/10/2016
Actual:
28/10/2016

Date of final study report
Planned:
31/12/2016

Actual:
18/04/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Development Centre Europe Ltd

Study protocol

ER-9531 TAKEDA Pioglitazone meta-analysis study protocol v1.2 20161104_clean.pdf
(330.93 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 topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:
Secondary data collection

Main study objective:
The primary research question is whether type 2 diabetes mellitus patients treated with pioglitazone are at a higher risk of bladder cancer compared to type 2 diabetes mellitus patients who are not treated with pioglitazone.

Study Design

Non-interventional study design
Systematic review and meta-analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
PIOGLITAZONE HYDROCHLORIDE

Medical condition to be studied
Bladder cancer

Population studied

Short description of the study population
Type 2 diabetes mellitus patients with or without exposure to pioglitazone with the risk of developing bladder cancer.

Age groups
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
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
99999999

Study design details

Outcomes
Bladder cancer

Data analysis plan
Hazard ratio will be the common measure of association that will be extracted from each study, or derived based on available data. Combined estimates will be derived using primarily a random-effects model and repeated secondarily using a fixed-effects model (sensitivity analysis).

Documents

Study results
Pioglitazone meta-analysis report abstract 2017-04-21.pdf(79.87 KB)

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Meta-analysis based on PubMed/Medline

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