

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

First published: 07/11/2016

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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 institutions and networks

Institutions

EPID Research Oy

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Institution

Contact details

Study institution contact

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Study contact

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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

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 use of data

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