# 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

**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

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

**Study institution contact**

Pasi Korhonen pasi.korhonen@epidresearch.com

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 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**

99.999.999

## 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

## 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 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