An observational study of patient cohorts who previously received long-term treatment with pioglitazone or placebo in addition to existing antidiabetic medications

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Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/15774

EU PAS number

EUPAS10513

Study ID

15774

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Latvia
- [ ] Lithuania
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Slovakia
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

The risk reduction by pioglitazone in cardiovascular (CV) outcomes in patients with Type 2 diabetes mellitus (T2DM) and pre-existing macrovascular disease was previously evaluated during PROactive study. This 10-year observational, multicenter study was conducted as a follow-up of PROactive study to investigate the CV and macrovascular effects observed with pioglitazone overtime during PROactive. In this study, high risk T2DM patients previously enrolled in PROactive were analyzed for long-term incidence, nature, and pattern of all malignancies in pioglitazone-treated and placebo-treated groups. The planned total duration of the study is 10 years, with data being analyzed

and reported every 2 years (starting July 2007). Patients were assessed at nominal visits every 6 months and every effort was made to obtain as much of the required information as possible.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Multiple centres: 18 centres are involved in the study

Contact details

Study institution contact

Erland Erdmann

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Erland Erdmann

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/11/2004

Actual: 02/11/2004

Study start date

Planned: 02/11/2004

Actual: 02/11/2004

Date of final study report

Planned: 19/07/2011

Actual: 19/07/2011

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

AD-4833-EC445-Protocol.pdf(259.56 KB)

AD-4833-EC445-Protocol Amendment 2.pdf(782.81 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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:

Combined primary data collection and secondary use of data

Main study objective:

The study aimed to investigate whether prior long term treatment of pioglitazone had any effect on the composite endpoint (including all-cause mortality, non-fatal myocardial infarction, coronary intervention, stroke, major leg amputation, bypass surgery or revascularisation in the leg, and the incidence, nature and pattern of newly diagnosed malignancies) in the PROactive enrolled T2DM patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PIOGLITAZONE

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

High risk type II diabetes mellitus (T2DM) patients previously enrolled in PROactive study, treated with pioglitazone or placebo in addition to their existing anti diabetic medication. Patients with completion of the final visit of the PROactive Study and willingness and ability to give written informed consent for the observational study were included.

Age groups

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

3599

Study design details

Outcomes

Primary outcome included the time from randomization to occurrence of first macro-vascular event or death (which includes all-cause mortality, non-fatal myocardial infarction, coronary intervention, stroke, major leg amputation, bypass surgery or revascularisation in the leg) in T2DM patients.

Data analysis plan

Kaplan-Meier method was used for calculating survival curves for pioglitazone and placebo. Estimates of the hazard ratio (HR) were calculated using Cox

model regression methods.

Documents

Study results

AD-4833-EC445-RDS-2015-07-15.pdf(61.02 KB)

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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