Cardiac profile of patients using rosiglitazone-containing anti-diabetes medicines: a study using the THIN database

First published: 06/10/2010

Last updated: 09/09/2016

Study Finalised

Administrative details

EU PAS number

EUPAS1591

Study ID

15148

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study is a retrospective analysis of a cohort of patients prescribed rosiglitazone based on the UK GP database, THIN. It suggests that about 8% of patients take rosiglitazone despite having cardiac contraindications as defined by the current SPC – congestive heart failure or acute coronary syndrome.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

European Medicines Agency

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jim Slattery

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/08/2010

Study start date

Actual: 13/08/2010

Date of final study report

Actual: 23/08/2010

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Off-label prescribing

Data collection methods:

Secondary use of data

Main study objective:

Discover how many patients receive rosiglitazone despite having cardiac contra-indications

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ROSIGLITAZONE

Population studied

Short description of the study population

Patients received at least one prescription of rosiglitazone-containing products in a clinical practice during a time window of 20 months from (April 1, 2008 through November 30, 2009).

Age groups

- 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)

Estimated number of subjects

10000

Study design details

Outcomes

Proportion of patients with cardiac contra-indications, Proportion of patients with history of heart failure

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Data analysis plan

Data and main analysisWe performed the study using The Health Improvement Network (THIN) database, patient receiving rosiglitazone were identified and then their medical history checked for events associated with either heart failure or acute coronary syndrome. Simple proportions were presented with confidence intervals.

Documents

Study results

Report_Rosiglitazone_use.pdf (151.59 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 source(s)

THIN® (The Health Improvement Network®)

Data sources (types)

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

No