

Impact of rosiglitazone safety alerts on oral antidiabetic sales trends: a country-wide study in Portugal

First published: 18/03/2016

Last updated: 01/04/2024

Study

Finalised

Administrative details

EU PAS number

EUPAS12872

Study ID

28116

DARWIN EU® study

No

Study countries

☐ Portugal

Study description

To assess the impact of rosiglitazone safety alerts on trends in the sale of rosiglitazone and other oral antidiabetic drugs. It was conducted an ecological study, using temporally aggregated data and linking safety alerts to country-wide sales of all oral antidiabetic drugs in Portugal from January 2002 to December 2012.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Sciences Institute of Biomedicine, University of Aveiro

☐ Portugal

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Institution

Educational Institution

ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maria Teresa Herdeiro

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/09/2012

Actual: 17/09/2013

Study start date

Planned: 07/01/2013

Actual: 04/02/2013

Date of final study report

Planned: 31/12/2016

Actual: 30/01/2016

Sources of funding

- Other

More details on funding

Internal funding

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess the impact of rosiglitazone safety alerts on trends in the sale of rosiglitazone and other oral anti diabetic drugs.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Ecological

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BG02) rosiglitazone

rosiglitazone

Population studied

Short description of the study population

Diabetic population using oral antidiabetic drugs.

Age groups

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

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

Diabetes mellitus patients

Estimated number of subjects

0

Study design details

Outcomes

Sales of rosiglitazone in Portugal from January 2002 to December 2012, Sales of all oral antidiabetic drugs in Portugal from January 2002 to December 2012

Data analysis plan

We conducted an ecological study, using temporally aggregated data and linking safety alerts to country-wide sales of all oral antidiabetic drugs in Portugal from January 2002 to December 2012

Documents

Study publications

[Herdeiro MT, Soares S, Silva T, Roque F, Figueiras A. Impact of rosiglitazone s...](#)

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)

[Drug dispensing/prescription data](#)

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