

Safety Alerts: An Observational Study in Portugal (Safety alerts)

First published: 03/02/2016

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Study

Finalised

Administrative details

EU PAS number

EUPAS11977

Study ID

17084

DARWIN EU® study

No

Study countries

 Portugal

Study description

An observational study of all alerts published on the INFARMED website from January 2002 through December 2014. From the data included in the alerts, the following information was extracted: active substance name (and trade name),

event that led to the alert, and the resulting safety measures. Active substances were classified according to the Anatomical Therapeutic Chemical (ATC) code.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Sciences Institute of Biomedicine, University of Aveiro

 Portugal

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Institution

Outdated

Educational Institution

ENCePP partner

Contact details

Study institution 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: 01/07/2015

Actual: 15/07/2015

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Analysis and description of safety alerts

Data collection methods:

Secondary use of data

Main study objective:

This study sought to analyze all safety alerts published by the Portuguese National Authority of Medicines and Health Products I.P. (INFARMED).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Sentinel sites

Population studied

Short description of the study population

Portuguese population

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)
-

Estimated number of subjects

0

Study design details

Data analysis plan

We conducted an observational study of all alerts published on the INFARMED website from January 2002 through December 2014. From the data included in the alerts, the following information was abstracted: active substance name (and trade name), event that led to the alert, and the resulting safety measures. Active substances were classified according to the Anatomical Therapeutic Chemical (ATC) code.

Documents

Study publications

[Soares S, Roque F, Teixeira Rodrigues A, Figueiras A, Herdeiro MT. Safety Alerts...](#)

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

Safety alerts, Infarmed website

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