

Emergency contraception. A safety and drug utilisation study in Spain

First published: 30/07/2012

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Study

Ongoing

Administrative details

EU PAS number

EUPAS2860

Study ID

8090

DARWIN EU® study

No

Study countries

 Spain

Study description

Emergency contraception has been a recent matter of debate in Spain. A fair and scientific-based approach is needed. To further learn upon the day after pill utilisation and safety, a combined cross-sectional (utilisation) and follow-up

(safety) study is carried out in a network community pharmacies

Study status

Ongoing

Research institutions and networks

Institutions

Universidad de Valladolid

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alfonso Carvajal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/01/2011

Actual: 10/01/2011

Study start date

Planned: 01/03/2011

Actual: 07/03/2011

Date of final study report

Planned: 31/03/2013

Sources of funding

- Other

More details on funding

CESME

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To learn the emergency contraceptives- induced adverse reactions in a real setting

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03AD) Emergency contraceptives

Emergency contraceptives

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

- Adults (46 to < 65 years)
-

Estimated number of subjects

400

Study design details

Outcomes

Whatever adverse reaction

Data analysis plan

Description, Risk estimation. Results of the follow-up study will be compared to those collected through spontaneous reporting.

Documents

Study publications

[Carvajal A, Sáinz M, Velasco V, García Ortega P, Treceño C, Martín Arias LH, Pe...](#)

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

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