

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

Alfonso Carvajal carvajal@ife.uva.es

Study contact

carvajal@ife.uva.es

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

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