# Emergency contraception. A safety and drug utilitation study in Spain

**First published:** 30/07/2012

**Last updated:** 30/11/2014

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 approch is needed. To further learn upon the day after pill utilitation and safety, a combined cross-sectional (utilitation) and follow-up

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

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Universidad de Valladolid

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution 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

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**Study start date**
Planned: 01/03/2011

Actual: 07/03/2011

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**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

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**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 spontaneus 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