A pregnancy exposure registry study to assess clinical follow-up and outcomes of pregnancies exposed to ulipristal acetate 30 mg

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Study Ongoing

Administrative details

EU PAS number

EUPAS33796

Study ID

49109

DARWIN EU® study

No

Study countries

Austria

Czechia

Finland

France
Germany
Greece
Ireland
Italy
Liechtenstein
Malta
Netherlands
Norway
Poland
Portugal
Romania
Spain
Switzerland
United Kingdom

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Arna Hrund Arnardóttir

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 27/03/2020

Actual: 19/05/2020

Study start date
Planned: 22/05/2020

Actual: 22/05/2020

Date of final study report
Planned: 21/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aristo Pharma GmbH, Aspen Healthcare Malta Limited, BIOGARAN, Eugia Pharma (Malta) Ltd., Exeltis Pharmaceuticals Holding, S.L., Farmitalia s.r.l, HELM AG, Medical Valley Invest AB, Mylan, Hexal AG, STADA Arzneimittel AG, Zentiva Group, a.s.

Study protocol

230530-Ulipristal-PASS-Protocol-v4.0_Redacted.pdf (2.5 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Post-marketing, non-interventional, web-based joint pregnancy registry.

Retrospective collection of pregnancy data and pregnancy outcomes.

Main study objective:

The primary objective of this pregnancy registry is to collect all data about pregnancy and pregnancy outcome in women exposed to ulipristal acetate 30mg for any reason, e.g. unrecognized pregnancy before intake or product failure.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-marketing, non-interventional, web-based joint pregnancy registry. Retrospective collection of pregnancy data and pregnancy outcomes.

Study drug and medical condition

Medicinal product name

ULIPRISTAL

Study drug International non-proprietary name (INN) or common name

ULIPRISTAL ACETATE

Anatomical Therapeutic Chemical (ATC) code

(G03AD02) ulipristal

ulipristal

Medical condition to be studied

Abortion

Ectopic pregnancy

Population studied

Short description of the study population

Pregnant women of any age in all European countries where the product will be launched are concerned, as far as they were exposed to Ulipristal 30 mg:

• during the menstrual cycle in which the pregnancy started or

• at any time during pregnancy.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

25

Study design details

Outcomes

“Effects on pregnancy maintenance/off-label use”,

“Risk of incomplete abortion and heavy bleeding”,

“Effects on foetus and newborns” and

“Risk of ectopic pregnancy”.

Data analysis plan

Descriptive statistics will be the primary approach for summarizing data from the pregnancy exposure registry. Data will be presented for all subjects enrolled in the registry. No stratified analysis is foreseen or has been planned for this study.

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

Pregnancy registry

Data sources (types), other

Exposure registry

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