An HCP survey-based active surveillance study to assess the safety of fixed dose combination of Levonorgestrel-Ethinyloestradiol (brand name Ovral-L) in the management of primary dysmenorrhea, endometriosis, and abnormal uterine bleeding among Indian females - Protocol# B6261001

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Study Planned

Administrative details

EU PAS number

EUPAS1000000606

Study ID

1000000606

DARWIN EU® study

No

Study countries

☐ India

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

Ketan.Asawale@pfizer.com

Primary lead investigator

Ketan Asawale

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/06/2025

Actual: 06/01/2025

Study start date
Planned: 01/02/2026

Date of final study report
Planned: 30/09/2026

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

Protocol # B6261001

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

PMS Study

Data collection methods:

Primary data collection

Study design:

Surveillance study

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name, other

Ovral-L (Levonorgestrel 0.15 mg and Ethinyloestradiol 0.03 mg)

Anatomical Therapeutic Chemical (ATC) code

(G03AA07) levonorgestrel and ethinylestradiol

levonorgestrel and ethinylestradiol

Medical condition to be studied

Dysmenorrhoea

Endometriosis

Abnormal uterine bleeding

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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

Not applicable