DARWIN EU® - Incidence and characterisation of polyendocrine metabolic ovarian syndrome in Europe

First published: 19/08/2026

Last updated: 01/10/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001090

Study ID

1000001090

DARWIN EU® study

Yes

Study countries

- Denmark
- Finland
- Netherlands
- Spain

United Kingdom

Study description

Polyendocrine metabolic ovarian syndrome (PMOS), previously named polycystic ovary syndrome (PCOS), is a common, heterogeneous endocrine disorder affecting females. PMOS is characterised by substantial heterogeneity in its clinical presentation, diagnosis, and management across healthcare settings.

A clear understanding of real-world pharmacologic management is needed to characterise how PMOS is treated in routine clinical practice.

However, analyses describing the use of pharmacological therapies following PMOS diagnosis and Real-World Evidence on the incidence of various health outcomes among individuals with PMOS remain limited.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution **Educational Institution** **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Norway
- Portugal
- Spain
- Sweden
- United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anna Saura-Lazaro

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2026

Actual: 01/07/2026

Study start date

Planned: 04/08/2026

Actual: 04/08/2026

Date of final study report

Planned: 14/11/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P5-C1-013_PMOS_V3.0.pdf (3.15 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Population-level descriptive disease epidemiology study (Objectives 1, 4, and 5)
Patient-level characterisation (Objectives 2 and 3)

Main study objective:

1. To estimate the incidence of recorded PMOS diagnoses over time.
2. To characterise individuals with PMOS at the time of recorded diagnosis in terms of age and pre-defined comorbidities.
3. To characterise individuals with PMOS in terms of pre-defined non-infertility drug treatments received following diagnosis.
4. To estimate the incidence rate of infertility, cardiovascular, and mental health outcomes in individuals with PMOS.
5. To estimate the 5-year and 10-year cumulative incidence of infertility, cardiovascular, and mental health outcomes in individuals with PMOS.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Polycystic ovarian syndrome

Additional medical condition(s)

Polyendocrine metabolic ovarian syndrome

Population studied

Short description of the study population

The study population will include all female individuals with the date of first PMOS diagnosis (index date) within the study period from 01/01/2010 to 31/12/2024.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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 source(s)

Danish Health Data Registries

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

Data source(s), other

FinOMOP-THL

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/cdm54.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No