DARWIN EU® - Treatment patterns in postmenopausal women in European countries: A real-world observational study

First published: 10/11/2025

Last updated: 11/03/2026

Study   Ongoing

Administrative details

EU PAS number

EUPAS1000000821

Study ID

1000000821

DARWIN EU® study

Yes

Study countries

☐ Denmark

☐ Germany

☐ Spain

☐ United Kingdom

Study description

Vasomotor symptoms (VMS), including hot flashes and night sweats, affect up to 80% of menopausal

women and significantly impair quality of life. Hormone replacement therapy (HRT) remains the primary

treatment for VMS, with various formulations and regimens available depending on clinical factors. Despite

its widespread use, there are risks associated with HRT, which vary by age, timing, and treatment type.

However, contemporary data on HRT utilisation patterns in Europe are limited, highlighting the need for

real-world evidence to inform regulatory decisions.

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Dina Vojinovic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/06/2025

Actual: 04/06/2025

Study start date

Planned: 24/10/2025

Actual: 24/10/2025

Date of final study report

Planned: 27/02/2026

Sources of funding

- EMA

Study protocol

[DARWIN EU_Protocol_P4-C1-013_Treatment patterns in postmenopausal women_V5.pdf](#) (1.45 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

Human medicinal product

Study topic, other:

Post-menopause

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort study will be conducted using routinely collected health data from 5 data sources
from 4 European countries belonging to 3 EU member states.

Main study objective:

The specific objectives of this study are:

1. To describe the demographic and clinical characteristics of postmenopausal women, including:

a) age,

b) body mass index (BMI),

c) smoking status,

d) concomitant conditions,

e) HRT used at treatment initiation, where applicable.

Estimates will be stratified by HRT status and presented for selected calendar years.

2. To estimate annual prevalence of HRT use among postmenopausal women, overall and
stratified by:

a) HRT formulation.

b) route of administration (systemic or local).

c) HRT type (natural or synthetic) (if feasible).

Estimates will additionally be stratified by age group at treatment initiation.

3. To estimate the duration of HRT use among postmenopausal women initiating HRT, overall, and

by age group.

4. To describe HRT treatment patterns among postmenopausal women over ten years following
HRT initiation, overall, and by age group.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03CA) Natural and semisynthetic estrogens, plain

Natural and semisynthetic estrogens, plain

(G03CB) Synthetic estrogens, plain

Synthetic estrogens, plain

(G03D) PROGESTOGENS

PROGESTOGENS

Population studied

Short description of the study population

The study population will include postmenopausal women defined as i) women aged 50 to 65 years and ii)
women aged <50 years with a prior history of conditions or procedures indicating premature or early

menopause. This definition will be applied consistently across study objectives.

Age groups
- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)

Study design details

Outcomes

The outcomes are as follows:

• Characterisation of postmenopausal women initiating HRT treatment or not on HRT (objective

1).

• Annual prevalence of HRT use among postmenopausal women, including formulations, route of

administration, and type of HRT (if feasible) (objective 2).

• Duration of HRT treatment among postmenopausal women (objective 3).

• Treatment patterns following HRT treatment initiation (objective 4).

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

IQVIA Disease Analyzer Germany

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

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/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No