DARWIN EU® - Sex differences in treatment patterns for primary hypertension in European countries

First published: 20/08/2026

Last updated: 20/08/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001092

Study ID

1000001092

DARWIN EU® study

No

Study countries

- Denmark
- Finland
- Netherlands
- Spain

United Kingdom

Study description

Emerging evidence suggests that biological sex may influence the development and progression of hypertension. Although females may be at an increased cardiovascular risk at lower blood pressure levels and often experience poorer blood pressure control following menopause, evidence informing sex-specific management remains scarce. Given the fragmented nature of the existing literature and the lack of consistent, large-scale Real-World Evidence across European healthcare systems, there is a need to better characterise potential sex differences in the management of pharmacological treatment of hypertension.

By evaluating sex-specific patterns in the initiation of antihypertensive drug treatment and subsequent treatment patterns among individuals with primary hypertension, this study aims to identify actionable gaps in care that may inform clinical, regulatory, and public health decision-making.

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

Ivan Lam

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/06/2026

Actual: 08/06/2026

Study start date

Planned: 03/08/2026

Actual: 03/08/2026

Date of final study report

Planned: 31/10/2026

Sources of funding

- EMA

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A cohort study will be conducted using routinely collected health data from 5 data sources from 5 countries across Europe

Main study objective:

1. To describe antihypertensive treatment initiation for primary hypertension in males and females
2. To describe drug utilisation of antihypertensive treatments, including initial treatment duration and initial dose, in males and females
3. To describe antihypertensive treatment switching patterns in males and females

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Antihypertensive drugs (ATC classes: C02, C03, C07, C08, C09)

Anatomical Therapeutic Chemical (ATC) code

(C02) ANTIHYPERTENSIVES

ANTIHYPERTENSIVES

(C03) DIURETICS

DIURETICS

(C07) BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

(C08) CALCIUM CHANNEL BLOCKERS

CALCIUM CHANNEL BLOCKERS

(C09) AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

Population studied

Short description of the study population

Objective 1 (Characterisation of antihypertensive drug treatment initiation)

Inclusion criterion: First ever diagnosis of primary hypertension during the recruitment period

Exclusion criteria

• Age <18 years at first diagnosis of primary hypertension (index date)

• Less than 365 days of available history before the index date

• Record of primary hypertension before index date

• Record of secondary hypertension on or before the index date

• Record of antihypertensive drug prescription/dispensation before the index date

Objectives 2 and 3 (Drug utilisation of treatment and characterisation of treatment switching patterns)

Inclusion criteria

• First ever diagnosis of primary hypertension during the recruitment period

• Initiation of antihypertensive drug treatment within 180 days after diagnosis (index date)

Exclusion criteria

• Age <18 years on the date of antihypertensive drug treatment initiation

• Less than 365 days of available history before the date of antihypertensive drug treatment initiation

• Record of primary hypertension before index date

• Record of secondary hypertension on the day of or before diagnosis of primary hypertension

• Record of antihypertensive drug prescription/dispensation before the first diagnosis of primary hypertension

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Age groups

- **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

Finnish Care Register for Health Care (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