DARWIN EU® - Representativeness of the clinical trial population compared with the real-world population with resistant hypertension

First published: 17/07/2026

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001065

Study ID

1000001065

DARWIN EU® study

Yes

Study countries

Belgium

Denmark

Finland

Netherlands

Spain

United States

Study description

Resistant hypertension is defined by elevated systolic and diastolic blood pressure values despite concomitant use of at least three antihypertensive drugs of different classes, usually including ACE-inhibitors/angiotensin receptor blockers, calcium channel antagonists, and diuretics, and is associated with an increased risk of myocardial infarction, stroke, end-stage renal disease, and death. Baxdrostat, an aldosterone synthase inhibitor, is under evaluation for marketing authorisation for the treatment of resistant hypertension. A recent clinical trial examined its efficacy and safety in individuals with uncontrolled or resistant hypertension. This study aims to assess the representativeness of the Baxdrostat trial population with resistant hypertension by estimating the demographic, clinical, and treatment characteristics of the real-world population with resistant hypertension.

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

Ellen Gerritsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/04/2026

Actual: 21/04/2026

Study start date

Planned: 25/06/2026

Actual: 25/06/2026

Date of final study report

Planned: 25/09/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P5-C1-002 P5-C2-003_Resistant hypertension_V4.0.pdf
(1.67 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:

A cohort study will be conducted using routinely collected health data from 7 data sources across 6 countries, including 5 European Union (EU) member states and the United States.

Main study objective:

1. To determine the extent to which the resistant hypertension trial population reflects the real-world resistant hypertension population by comparison of demographic (age, sex), clinical, and treatment characteristics observed in the clinical trial with those derived from real-world data sources.
2. To characterise patients with resistant hypertension, including but not limited to age, sex, BMI/obesity status, chronic kidney disease stage, diabetes, atrial fibrillation, cardiovascular disease (aldosteronism), current treatment of care, and other relevant comorbidities.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

resistant hypertension

Population studied

Short description of the study population

For characterisation (objectives 1–2), the study population will include adults with resistant hypertension identified within routinely collected healthcare data

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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)

Study design details

Setting

This study will be conducted using routinely collected data from 7 primary care, hospital, and registry data sources in the DARWIN EU® Network of data partners from 6 countries, including 5 EU member states and the United States (Table 1, ANNEX I). All data were a priori mapped to the OMOP CDM.

Outcomes

The outcomes will be as follows:

• Characterisation of individuals with resistant hypertension (objectives 1–2)

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)

University Hospital Antwerp structured data

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

The Information System for Research in Primary Care (SIDIAP)

Integrated Primary Care Information (IPCI)

Data source(s), other

IQVIA US - Ambulatory EMR

Data sources (types)

Electronic healthcare records (EHR)

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