

# DARWIN EU® - Characterisation of aliskiren users

**First published:** 06/10/2025

**Last updated:** 27/01/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000768

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### Study ID

1000000768


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### DARWIN EU® study

Yes


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### Study countries

 Denmark

 Netherlands

 Spain

 United Kingdom

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### Study description

Existing evidence from case reports and preclinical data raised concerns regarding the atrial and ventricular proarrhythmic potential of aliskiren, especially with underlying risk of atrial fibrillation. However, little is known about the usage of aliskiren in clinical practice, in particular characteristics of aliskiren users.

This study aims to characterise new aliskiren users to inform the planning and feasibility of a potential future safety study investigating risk of cardiac events.

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## Study status

Finalised

## 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

Natasha Yefimenko [study@darwin-eu.org](mailto:study@darwin-eu.org)

**Study contact**

[study@darwin-eu.org](mailto:study@darwin-eu.org)

## Primary lead investigator

Amy Lam

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 21/07/2025

Actual: 21/07/2025

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### Study start date

Planned: 09/09/2025

Actual: 09/09/2025

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### Date of final study report

Planned: 31/12/2025

Actual: 10/12/2025

## Sources of funding

- EMA

## Study protocol

[DARWIN EU\\_Protocol\\_P4-C1-017\\_Characterisation of aliskiren users\\_V3.0.pdf](#)

(975.87 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

A cohort study will be conducted using routinely collected health data from 4 databases from 4 countries across Europe and in 3 EU member states.

**Main study objective:**

1. To characterise new aliskiren users in terms of demographics, comorbidities, duration of use, and potential indications for aliskiren use, overall and stratified by age and by sex, during the study period of 2007–2014 and 2015–2024.
2. To assess the use of co-medication, both prior to and after new aliskiren treatment initiation, overall and stratified by age and by sex, during the study period of 2007–2014 and 2015–2024.
3. To estimate the number of people with both at least one aliskiren prescription/dispensation record(s) and a record of pre-specified cardiac events anytime during the study period of 2007–2014 and 2015–2024 (cross-cohort counts), overall and stratified by age and sex.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name, other**

Aliskiren

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### **Study drug International non-proprietary name (INN) or common name**

ALISKIREN

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### **Anatomical Therapeutic Chemical (ATC) code**

(C09XA02) aliskiren

aliskiren

## Population studied

## Short description of the study population

### Inclusion criteria

- All individuals with an aliskiren prescription or dispensing record within the study period: 01/01/2007 to 31/12/2014, and from 01/01/2015 to 31/12/2024 (or the latest available date)

### Exclusion criteria

- Individuals starting first ever aliskiren with less than 365 days prior database history
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## Age groups

- **In utero**

- **Paediatric Population (< 18 years)**

- Neonate
  - Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)
- 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)

## Documents

## Study report

[DARWIN EU\\_Report\\_P4-C1-017\\_Characterisation\\_of\\_aliskiren\\_users\\_V2.0.pdf](#)

(1.59 MB)

[Shiny App](#)

## 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 Care Registries

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

## **CDM mapping**

Yes

## **CDM Mappings**

### **CDM name**

OMOP

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### **CDM website**

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

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### **CDM version**

<https://ohdsi.github.io/CommonDataModel/index.html>

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

No