DARWIN EU® - Characterisation of aliskiren users

First published: 06/10/2025

Last updated: 05/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000768

Study ID

1000000768

DARWIN EU® study

Yes

Study countries

- [ ] Denmark
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

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.

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

Natasha Yefimenko study@darwin-eu.org

Study contact

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

Study start date

Planned: 09/09/2025

Actual: 09/09/2025

Date of final study report

Planned: 31/12/2025

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

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 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

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

ALISKIREN

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)

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

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/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No