DARWIN EU® - Association between aliskiren use and the incidence of cardiac arrhythmia and/or sudden death

First published: 20/08/2026

Last updated: 20/08/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001094

Study ID

1000001094

DARWIN EU® study

Yes

Study countries

Denmark

Spain

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, current clinical evidence regarding the risk of cardiac arrhythmia and/or sudden death with aliskiren use is scarce

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

Amy Lam

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/03/2026

Actual: 03/05/2026

Study start date
Planned: 02/07/2026

Actual: 02/07/2026

Date of final study report
Planned: 27/11/2026

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 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 SCCS will be conducted using routinely collected health data from 4 data sources from 2 European Union (EU) member states

Main study objective:

The objective of this study is to identify and characterise aliskiren users with cardiac arrhythmia and/or sudden death during the study period of 2007–2025, and to estimate the risk of cardiac arrhythmia and/or sudden death by calculating incidence rate ratio in different risk periods relative to the unexposed baseline period

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Aliskiren

Medical condition to be studied

Sudden death

Additional medical condition(s)

Cardiac arrhythmia

Population studied

Short description of the study population

Inclusion criteria

• Present in the period of 01/01/2007–31/10/2025 (or the end of available data)

• At least one aliskiren prescription or dispensing record

• At least one record of any event included in the composite outcome consisting of cardiac arrhythmia (atrial fibrillation, atrial arrhythmias other than atrial fibrillation, or ventricular arrhythmias) or sudden death (sudden or unexplained death, sudden cardiac death, or unattended death)

Exclusion criteria

• Missing information on age or sex

• Less than 365 days of data availability prior to first aliskiren prescription or dispensing record

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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 Data Registries

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)

The Valencia Health System Integrated Database

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