

# RELATIVE EFFECTIVENESS OF DRONEDARONE VS. OTHER TREATMENTS OF ATRIAL FIBRILLATION (EFFECT-AF)

**First published:** 11/01/2013

**Last updated:** 30/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS3351

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### Study ID

18345

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### DARWIN EU® study

No

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### Study countries

 Germany

 Italy

 Spain

 United States

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## Study description

This is an international observational multicentre study to be conducted in Germany, Spain, Italy and USA. The main objective of the study is to evaluate the relative effectiveness of dronedarone in real world clinical practice versus other anti-arrhythmic agents of interest. The design of the study is a historic-prospective cohort with dynamic exposure and stratified competitive recruitment with balanced comparison groups of dronedarone versus alternative antiarrhythmic drugs of interest.

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## Study status


Finalised

## Research institutions and networks

### Institutions

#### Real World Studies, LA-SER Research

 France

 United Kingdom

**First published:** 23/03/2012

**Last updated:** 23/03/2012

Institution

Outdated

Other

ENCePP partner

Multiple centres: 170 centers are involved in the study

## Contact details

### Study institution contact

Artak Khachatryan artak.khachatryan@la-ser.com

Study contact

[artak.khachatryan@la-ser.com](mailto:artak.khachatryan@la-ser.com)

### Primary lead investigator

Artak Khachatryan

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 11/10/2012

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### Study start date

Planned: 01/04/2013

Actual: 18/03/2013

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### Date of interim report, if expected

Actual: 12/02/2016

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### Date of final study report

Planned: 28/02/2017

Actual: 30/01/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi-Aventis R&D

## 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:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

To evaluate the relative effectiveness of dronedarone in real world clinical practice versus other anti-arrhythmic agents.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(C01BA) Antiarrhythmics, class Ia

Antiarrhythmics, class Ia

(C01BC) Antiarrhythmics, class Ic

Antiarrhythmics, class Ic

(C01BD01) amiodarone

amiodarone

(C01BD07) dronedarone

dronedarone

(C07AA07) sotalol

sotalol

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## **Medical condition to be studied**

Atrial fibrillation

## Population studied

### **Short description of the study population**

Historic-prospective cohort of atrial fibrillation in Germany, Spain, Italy and USA who were exposed to dronedarone or alternative antiarrhythmic drugs of interest.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with atrial fibrillation

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### **Estimated number of subjects**

1009

## Study design details

## Outcomes

Recurrence of Atrial Fibrillation, Cardiovascular hospitalisation, AV node ablation and catheter ablation for Atrial Fibrillation (AF), Progression to permanent AF, Clinical progression to heart failure and left ventricular systolic dysfunction  
Congestive heart failure, Interstitial pulmonary disease, Liver injury/toxicity, Renal insufficiency/failure, Cerebrovascular accident/Stroke, Myocardial infarction, Torsade de pointes, Death

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## Data analysis plan

The following principles of the analysis may be employed:

- Dynamic population time for denominators.
- Events of interest to be considered as discrete.
- Same patient may contribute population-time to different exposures.
- Autocorrelation between events/within patients' denominators will be considered using GEE or mixed effects models.
- Propensity score methods and inverse probability weighted estimators will be used to enhance comparative validity and account for underrepresented patient populations in the enrolled study sample.

## 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 sources (types)**

Other

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### **Data sources (types), other**

Prospective patient-based data collection, Retrospective patient-based data collection

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## 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**

Unknown