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

Study ID

18345

DARWIN EU® study

No

Study countries

Germany

Italy

Spain

United States

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.

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Institution | Outdated | Other | ENCePP partner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

Primary lead investigator

Artak Khachatryan

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/10/2012

Study start date

Planned: 01/04/2013

Actual: 18/03/2013

Date of interim report, if expected

Actual: 12/02/2016

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

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

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

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

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

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

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)

Special population of interest

Other

Special population of interest, other

Patients with atrial fibrillation

Estimated number of subjects

1.009

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

---

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown