Effectiveness, safety and efficiency of the use of vernakalant in the control of the rhythm of atrial fibrillation in the emergency. Cohort study (VERITA)

First published: 15/02/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS103551

Study ID

103552

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Atrial fibrillation (AF) is the most prevalent sustained arrhythmia in clinical practice in hospital emergency departments. Complications of AF include thromboembolism and heart failure. In addition, affected patients may be at increased risk of mortality. Within the acute management of AF, two different strategies should be considered: rate control (usually with a beta-blocker or calcium channel inhibitor) and rhythm control (electrical or pharmacological cardioversion). Rhythm and rate control strategies are associated with similar rates of mortality and morbidity, such as embolic risk. The decision to adopt a therapeutic strategy is usually dictated by the presence of symptoms associated with AF and/or the development of left ventricular systolic dysfunction believed to be secondary to the arrhythmia. According to the ESC guidelines, there are different options for pharmacological cardioversion: flecainide and propafenone (class Ic antiarrhythmics), intravenous amiodarone, and vernakalant. Other alternatives, such as dofetilide and ibutilide, are not marketed in Europe. On June 24, 2010, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending the marketing authorization of vernakalant, indicated for the rapid conversion to sinus rhythm of AF. of recent onset in adults. For its part, the United States Food and Drug Administration (FDA) denied the marketing application for vernakalant due to safety concerns: severe hypotension, ventricular arrhythmias, conduction abnormalities, and death. Currently, the management in terms of AF rhythm control in emergency services varies depending on the idiosyncrasy of each hospital and its own experience of use. In this context, a retrospective observational study is proposed to evaluate the efficiency and safety of vernakalant in clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Puerta de Hierro-Majadahonda University Hospital

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Institution

Contact details

Study institution contact

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Primary lead investigator

Ruiz-Antorán Belén

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/06/2022

Actual: 06/06/2022

Study start date

Planned: 01/09/2022

Actual: 01/09/2022

Data analysis start date
Planned: 31/10/2023

Actual: 14/02/2023

Date of interim report, if expected
Planned: 29/12/2023

Actual: 14/02/2023

Date of final study report
Planned: 01/06/2024

Actual: 14/02/2023

Sources of funding

- Other

More details on funding

The study is not funded

Study protocol

PROTOCOLO ESTUDIO VERNAKALANT EN URGENCIAS VERSION 25052022.pdf

(222.45 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the effectiveness and safety of vernakalant for the rhythm control of AF in the context of clinical practice, in comparison with its treatment alternatives.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multicenter retrospective, post-authorization drug study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(C01BG11) vernakalant

vernakalant

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients diagnosed with atrial fibrillation received treatment with vernakalant, amiodarone, flecainide, propafenone or electrical cardioversion from 2012 to

2022.

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

Atrial fibrillation patients

Estimated number of subjects

352

Study design details

Outcomes

Percentage of patients with reversion to sinus rhythm in the first hour after treatment, - Percentage of patients with reversion to sinus rhythm in the first 12 hours/24 hours. - Percentage of patients requiring hospitalization. - Hospital stay - Percentage of patients with AF recurrence in the first 5 days/ 30 days/ 6 months

Data analysis plan

The incidence in exposed (cohort treated with vernakalan and in non-exposed (treated with other cardioversión drug) will be calculated for each of the

effectiveness variables. From these, the measures of association relative risk (RR), absolute risk reduction (RAR) and relative risk reduction (RRR) will be calculated for each of the variables, with their 95% CIs. The RR adjusted for comorbidities and prognostic factors will be estimated.

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)

Electronic healthcare records (EHR)

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

No