A prospective observational registry study to characterise normal conditions of use, dosing and safety following administration of vernakalant IV sterile concentrate

First published: 20/07/2011

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Study Finalised

Administrative details

EU PAS number

EUPAS2078

Study ID

26663

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Denmark
- ☐ Finland

☐ Germany

☐ Spain

☐ Sweden

Study description

This non-interventional prospective study is a post-authorization safety study of vernakalant conducted to collect information about normal conditions of use and appropriate dosing, and to quantify possible medically significant risk associated with the use of vernakalant in real-world clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Gyermek háziorvosi rendelő

Multiple centres: 45 centres are involved in the study

Contact details

Study institution contact

Bhirangi Kiran ndunkel@correvio.com

Study contact

ndunkel@correvio.com

Primary lead investigator

Bhirangi Kiran

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/01/2010

Actual: 05/01/2010

Study start date

Planned: 30/09/2011

Actual: 02/09/2011

Data analysis start date

Planned: 09/05/2018

Actual: 14/07/2018

Date of final study report

Planned: 30/07/2018

Actual: 29/10/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Correvio International

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

To collect information about normal use and appropriate dosing and quantify possible medically significant risks associated with the use of vernakalant in real-world clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Sentinel sites, Observational Study

Study drug and medical condition

Name of medicine

BRINAVESS

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Atrial fibrillation patients with vernakalant IV administration.

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

2000

Study design details

Outcomes

# of participants experiencing: significant hypotenstion, significant ventricular arrhythmia, significant atrial flutter, significant bradycardia, # of participants who are converted to sinus rhythm for at least 1 minute up to 90 minutes after the start of first infusion of vernakalant

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Data analysis plan

Frequencies and cumulative incidence of health outcomes of interest (HOIs) and serious adverse events (SAEs) following vernakalant IV administration will be

reported for the 24-hour follow-up period, or until end of medical encounter, whichever occurs earlier. Ninety-five percent confidence intervals for the cumulative incidence measures for HOIs will be computed.

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)

Other

Data sources (types), other

Prospective 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