Ivabradine Drug Utilisation Study in Select European Countries: A Multinational, Retrospective, Observational Study to Assess Effectiveness of Risk-Minimisation Measures

First published: 20/06/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19522

Study ID

26650

DARWIN EU® study

No

Study countries

France

Germany

Italy

Spain

United Kingdom

Study description

This is a multinational retrospective drug utilization study aiming to assess how ivabradine is used in patients with chronic stable angina pectoris in routine clinical practice, and to evaluate the effectiveness of the new risk-minimisation measures (RMM) with a focus on whether the new contraindications (heart rate (HR) at treatment initiation lower than 70 bpm and concomitant use of verapamil or diltiazem) are followed.

Study status

Finalised

Research institutions and networks

Institutions

Real World Solutions, PRA Real World Solutions

France

Germany

First published: 19/05/2021

Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alexandre Malouvier

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/06/2016

Actual: 10/06/2016

Study start date

Planned: 31/12/2016

Actual: 14/07/2017

Data analysis start date

Planned: 02/04/2018

Date of interim report, if expected

Planned: 31/12/2017

Actual: 12/12/2017

Date of final study report

Planned: 30/06/2018

Actual: 28/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Les Laboratoires Servier

Study protocol

0304114 Ivabradine DUS_PASS_Amend-2 1_Final_28Apr2016.pdf (1015.16 KB)

Redacted Protocol-version 2.2.pdf (3.15 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess how ivabradine is used in chronic angina patients and to describe before and after implementation of the new RMM:-Characteristics of new users according to demographics and specific comorbidities at baseline and baseline HR at treatment initiation-Patterns of use according to the dose and the concurrent use of verapamil or diltiazem at initiation and within a 6-month follow-up period

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective cohort study/Chart review

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

IVABRADINE

Anatomical Therapeutic Chemical (ATC) code

(C01EB17) ivabradine

ivabradine

Medical condition to be studied

Angina pectoris

Population studied

Short description of the study population

All patients with chronic stable angina initiating treatment with ivabradine in regular clinical practice. A patient initiating ivabradine (new user) was defined as a patient without documented use of ivabradine during the previous 6 months and who receives a first prescription for ivabradine by their prescribing physician during (one of) the study periods.
Patients with documented initiation of treatment with ivabradine during one of the study periods, diagnosis of chronic stable angina as the indication for treatment initiation, and patient (or legal representative) who has provided informed consent to participate in the study, where required were included.

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

Angina pectoris patients

Estimated number of subjects

1.200

Study design details

Outcomes

For each study period:-HR at treatment initiation-Ivabradine dose at initiation and dose changes within a 6-month follow-up (FU)-Concurrent use of verapamil or diltiazem at baseline and within a 6-month FU-Ivabradine prescriptions according to the HR recommendation at baseline, no doses higher than the SmPC doses at initiation and during FU,and no concomitant use of verapamil or diltiazem, -Characteristics of participating and non-participating physicians-Patient’s characteristics and treatment patterns at start date.-Ivabradine treatment discontinuation curves by study period

Data analysis plan

All analyses (primary and secondary) will be stratified by study period, unless specified otherwise. The difference, before and after implementation of the additional RMM, between the proportions of the study outcomes defined in the main analysis will be calculated as an estimate of the change. In addition to analyses based on the overall population the primary and secondary outcomes will be presented by country, by physician specialty, and by type of setting for

specialists. Ivabradine dose at start and over the 6-month FU will be stratified by age group. A chi-square test or a t-test will be used to test the differences (95% CI) in patient characteristics and observed study outcomes between the two study periods. As sensitivity analyses, the primary outcome will be:evaluated on the whole study cohort, including patients with missing data in the denominator for proportions, summarized by initiator status (initiator vs subsequent prescriber)

Documents

Study results

Ivabradine DUS - Final Report Abstract.pdf (130.76 KB)

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

Patients medical charts

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