Post-authorisation safety study (PASS) to evaluate risk minimisation measures for medication errors with Uptravi during the titration phase in patients with pulmonary arterial hypertension (PAH) in clinical practice (EDUCATE)

First published: 15/10/2018

Last updated: 03/12/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS25699

Study ID

47541

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Poland
- [ ] Spain
- [ ] United Kingdom

Study description

The study is an observational, cross-sectional survey of awareness, knowledge, and self-reported behaviour among a sample of health care professionals (HCPs) and patients at completion of titration or discontinuation of Uptravi during titration. This survey will be administered as a web-based questionnaire (HCPs and patients)

Study status

Ongoing

Research institutions and networks

Institutions

Parexel International

- [ ] United States

First published: 19/10/2010

Last updated: 10/12/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Audrey Muller

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2018

Study start date

Planned: 01/12/2020

Actual: 01/12/2018

Date of final study report

Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Actelion Pharmaceuticals Ltd

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:

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:

The objectives of this study are to describe HCPs’ and patients’ awareness (process), knowledge (impact), and comprehension (impact) of the RMM (risk minimisation measures) and to record the occurrence of patient-reported “wrong dose” medication errors (outcome) at completion of titration or discontinuation of Uptravi during titration.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

UPTRAVI

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

SELEXIPAG

Anatomical Therapeutic Chemical (ATC) code

(B01AC27) selexipag

selexipag

Medical condition to be studied

Pulmonary arterial hypertension

Population studied

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)

Estimated number of subjects

260

Study design details

Outcomes

Outcome is defined per ARMM (Additional risk minimization measures) effectiveness indicators: process, impact and outcome (i.e. patient-reported medication errors). Process refers to indicators to determine the dissemination of the ARMM and any instructions received from the HCP regarding the titration process. Impact involves questions to measure knowledge, comprehension, actions, and behavior associated with the use of Uptravi.

Data analysis plan

Data analyses will be descriptive in nature and will focus on summarising the questionnaire responses from HCPs and patients, information on characteristics of the respondents, and medical chart–recorded PAH characteristics. Summary tables consisting of frequencies with percentages and 95% CIs for the proportion of correct responses will be created for all questionnaires. Results will be analysed and presented by country and by relevant variables, if the study size permits.

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

Survey

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