Evaluation of the effectiveness of Penthrox® (methoxyflurane) educational tools adopted as additional risk minimisation measures: Healthcare professional and Patient Survey (Penthrox-Survey)

First published: 05/04/2016

Last updated: 01/04/2024

Study | Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/29622

EU PAS number

EUPAS13034

Study ID

29622

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

As a condition to the marketing authorisation of Penthrox (methoxyflurane), a HCP administration guide and checklist and a patient alert card have been developed to increase awareness of important risks associated with methoxyflurane use and of the best course of actions to minimise those risks. In line with regulatory guidance, a survey of HCPs and patients is proposed to assess whether the processes put in place for the Penthrox educational efforts are effective in achieving a desirable understanding of and behaviour upon key safety messages related to the use of Penthrox.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution | Laboratory/Research/Testing facility | Non-Pharmaceutical company | ENCePP partner

National Institue for Health Research (UK), Multiple centres: 16 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2016

Study start date

Planned: 15/10/2016

Actual: 15/12/2016

Date of final study report
Planned: 30/07/2018

Actual: 14/02/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Medical Developments International

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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:

The main objective is to measure awareness, usage, readability, knowledge and understanding of the messages, and impact on behavioural implementation of key safety information contained in the HCP administration guide and checklist, and in the patient alert card among HCPs and patients.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine, other

Penthox

Medical condition to be studied

Pain management

Population studied

Short description of the study population

Healthcare professional and Patients who had received Penthrox® (methoxyflurane) educational tools.

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

250

Study design details

Outcomes

To measure awareness, usage, readability, knowledge and understanding of the messages, and impact on behavioural implementation of key safety information contained in the HCP administration guide and checklist, and in the patient alert card among HCPs and patients. - Major determinants of HCP and patient understanding and implementation regarding key messages. - Measures of awareness, usage, readability, knowledge, understanding and behaviour reported by HCPs and patients in the survey will be correlated with clinical data

collected in the context of the twin PASS.

Data analysis plan

Analyses will be mainly descriptive in nature. Categorical data will be summarized by counts and percentages. Continuous data will be summarized using number, mean, standard deviation (SD), median, quartiles, minimum and maximum and in the case of non-normally distributed data, median, range and interquartile range. All statistical tests will be 2-sided and conducted at the 0.05 alpha level. P-values will be presented to three decimal places. A detailed statistical analysis plan (SAP) will be developed and approved before final database lock and will include methods of analysis and presentation and table shells.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Survey questionnaire

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