Post Authorisation Safety Study (PASS) to Evaluate the Risks of Hepatotoxicity and Nephrotoxicity from Administration of Methoxyflurane (Penthrox®) for Pain Relief in Hospital Accident & Emergency Departments in the United Kingdom (Penthrox-PASS)

First published: 05/04/2016

Last updated: 15/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS13040

Study ID

30864

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Medical Developments UK Ltd (MDI) has applied for marketing authorisation of a liquid oral inhalation preparation of methoxyflurane (Penthrox®), for emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain, via the decentralised procedure with the Medicines and Healthcare products Regulatory Agency (MHRA). Certain safety issues (hepatotoxicity and nephrotoxicity) have been identified by the MHRA medical assessor as potential public health risks. A PASS (and risk minimisation measures which are being evaluated separately from this study) has been recommended with the primary purpose of confirming the absence of a significant risk of hepatotoxicity with use of methoxyflurane in Accident and Emergency (A&E) during routine pre-hospital clinical practice, and in hospital A&E departments.

Study status

Ongoing

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

Networks

NIHR Medicines for Children Research Network

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nawab Qizilbash

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 05/01/2016

Study start date
Planned: 14/08/2016

Actual: 15/12/2016

Data analysis start date
Planned: 01/12/2019

Date of interim report, if expected
Planned: 15/02/2019

Date of final study report
Planned: 31/01/2020

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

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

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

METHOXYFLURANE

Medical condition to be studied

Pain management

Population studied

Short description of the study population

250 patients for the patient survey and 250 HCPs for the HCP survey

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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.

Documents

Study publications

Qizilbash, N., Kataria, H., Jarman, H. et al. Real world safety of methoxyflura…

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 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

No