

# 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

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### Study ID

30864


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### DARWIN EU® study

No

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## Study countries

 United Kingdom

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## 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.

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## 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

Nawab Qizilbash [oxon@oxonepi.com](mailto:oxon@oxonepi.com)

**Study contact**

[oxon@oxonepi.com](mailto:oxon@oxonepi.com)

### Primary lead investigator

Nawab Qizilbash

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 05/01/2016

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**Study start date**

Planned: 14/08/2016

Actual: 15/12/2016

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**Data analysis start date**

Planned: 01/12/2019

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**Date of interim report, if expected**

Planned: 15/02/2019

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**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

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

Non-EU RMP only

## Methodological aspects

**Study type:**

Non-interventional study

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**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

**Medicinal product name, other**

Penthox

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

METHOXYFLURANE

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**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)
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### **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.

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### **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...](#)

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## 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](#)

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### Data sources (types), other

Survey questionnaire

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No