Modified Prescription-Event Monitoring Study to Monitor the Introduction of Atrovent Inhaler CFC-Free® MDI in the United Kingdom (Atrovent CFC-free M-PEM)

First published: 16/04/2014

Last updated: 16/02/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS6352

Study ID

6353

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This was a modified prescription event monitoring (M-PEM) study to monitor the safety of Atrovent® CFC-free MDI following a switch from CFC-containing propellants. M-PEM is a non-interventional prospective observational study methodology. The exposure data comprise information from prescriptions collected by the NHS Business Services Authority (NHSBSA) in England. The outcome data are event reports during three month pre- and post-exposure periods, obtained by sending questionnaires to the general practitioners (GPs) who issued prescriptions for Atrovent® CFC-free MDI.

Study status

Finalised

Research institutions and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom

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Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Saad Shakir

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 05/05/2004

Study start date
Actual: 06/05/2004

Date of final study report
Actual: 06/07/2010

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To actively monitor the safety of the introduction of Atrovent® CFC-free MDI into general practice in England, for both adults and children.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Medicinal product name, other

Atrovent CFC-free MDI

Population studied

Short description of the study population

General practitioners (GPs) who issued prescriptions for Atrovent® CFC-free MDI.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Term newborn infants (0 – 27 days)
- 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

13.211

Study design details

Data analysis plan

Incidence densities for events occurring three months prior to and in the first three months of exposure to Atrovent® CFC-Free MDI were calculated, together with incidence density ratios to compare event rates before and during exposure. A matched analysis of specific events occurring in the three-month before and three-month after exposure period was performed to produce risk ratios.

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

Prescription event monitoring

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