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

PURI
https://redirect.ema.europa.eu/resource/6353

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 institution and networks

Institutions

Drug Safety Research Unit (DSRU)

United Kingdom
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16/02/2024

Institution
ENCePP partner
Not-for-profit

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:
05/05/2004

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

Name of medicine, 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
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Children (2 to < 12 years)
Adolescents (12 to < 18 years)
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
13211

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

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