Characteristics of asthma patients at risk of failed Diskus use in primary care: a retrospective cohort study

First published: 18/11/2013

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/27566

EU PAS number

EUPAS5171

Study ID

27566

DARWIN EU® study

No

Study countries

☐ Australia

- [ ] France
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Retrospective, cross-sectional, observational, database analysis using theinternational dataset: implementing Helping Asthma in Real Patients (iHARP) for describing characteristics of patients at risk of making critical errors in usage of DPI Diskus for there asthma.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

- [ ] United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

Victoria Carter

Study contact

victoria@opri.sg

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2013

Actual: 01/11/2013

Study start date

Planned: 03/01/2011

Actual: 03/01/2011

Data analysis start date

Planned: 07/10/2013

Date of final study report
Planned: 07/01/2014

Actual: 15/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TEVA

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

Describe characteristics of patients at risk of failed diskus use

Study Design

Non-interventional study design

Cross-sectional

Population studied

Short description of the study population

Patients 16 years and older, who have a current diagnosis of asthma and have received two or more prescriptions for fixed-dose combination ICS/long-acting beta-agonist(LABA) therapy in the year before the review.

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

500

Study design details

Outcomes

Characteristics, Risk assessment

Data analysis plan

We evaluated patient subjective and objective usage of inhaler, patient demographic characteristics, smoking state and comorbidity and asthma outcome were obtain from the iHARP database.

Documents

Study publications

Westerik JA, Carter V, Chrystyn H, Burden A, Thompson SL, Ryan D, Gruffydd-Jone...

Data management

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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