Effectiveness of Dymista® in patients with allergic rhinitis and asthma

First published: 13/08/2019

Last updated: 01/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30941

EU PAS number

EUPAS30940

Study ID

30941

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A pre-post historical cohort study evaluating the effectiveness of a novel combination therapy of antihistamine and intranasal corticosteroid (Dymista®) on asthma-related outcomes among patients with allergic rhinitis and asthma multi-morbidity. The primary objective is to examine the effectiveness of Dymista® in terms of improving asthma control by comparing the number of acute respiratory events and other measures of asthma control in the year before and after initiation of Dymista®.

Study status

Ongoing

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

David Price

Study contact

dprice@rirl.org

Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/05/2019

Actual: 25/02/2019

Study start date

Planned: 24/05/2019

Actual: 24/04/2019

Data analysis start date

Planned: 24/05/2019

Actual: 24/04/2019

Date of final study report

Planned: 23/08/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mylan

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To examine the effectiveness of Dymista® in terms of improving asthma control by comparing the number of acute respiratory events and other measures of asthma control in the year before and after initiation of Dymista®.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Dymista

Anatomical Therapeutic Chemical (ATC) code

(R01) NASAL PREPARATIONS

NASAL PREPARATIONS

Medical condition to be studied

Asthma

Rhinitis allergic

Population studied

Short description of the study population

Asthma patients, aged ≥12 years who initiated Dymista® for treatment of allergic rhinitis.

Patients with following criteria were included:

• Initiation of Dymista® (patients receive ≥1 prescription of Dymista® any time)

• Diagnosis of asthma ever: diagnostic read code ever following the Quality Outcomes Framework (QOF)

• Age ≥12 years at IPD;

• Active asthma, defined as ≥1 prescription for an inhaler (reliever or controller) in the year prior to and including IPD

• Continuous electronic medical data for ≥1 year prior to IPD

• ≥1 year of electronic medical data after IPD

Age groups

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)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

1188

Study design details

Outcomes

Change in the number of acute respiratory events was defined as occurrence of any of the following events separately or together (occurrences within 14 days of each other were considered to belong to the same event). Change in the number of asthma exacerbations, GINA treatment step, asthma control (Risk Domain Asthma Control and Overall Asthma Control), average daily dose of SABA and control of asthma symptoms (GINA level control)

Data analysis plan

Patients initiating Dymista® were identified. The number of acute respiratory events in the baseline year and outcome year were determined. The effectiveness of Dymista® on the number of acute respiratory events in the baseline year was compared with the number of events in the outcome year by using the Wilcoxon signed rank test (for paired data). The results were reported as the proportion of patients who improved, worsened and stayed stable in the number of, for instance, acute respiratory events.

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

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