Observational study to evaluate the actual use of Dymista® nasal spray in different allergic rhinitis patient phenotypes

First published: 12/03/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS23075

Study ID

34843

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Germany
- ☐ Hungary
- ☐ Ireland

Netherlands

Study description

The objective of this non-interventional study is gathering knowledge on patient phenotypes getting the same prescription for allergic treatment for the first time in routine clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 137 centres are involved in the study

Contact details

Study institution contact

Melanie Emmeluth melanie.emmeluth@mylan.com

Study contact

melanie.emmeluth@mylan.com

Primary lead investigator

Melanie Emmeluth

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/03/2017

Study start date
Actual: 08/02/2018

Data analysis start date
Actual: 30/04/2019

Date of final study report
Actual: 20/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MEDA Pharma GmbH & Co. KG

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To gather knowledge on patient phenotypes getting the same prescription for allergic treatment for the first time in routine clinical practice. The response to therapy in routine clinical practice, quality of sleep as well as troublesomeness in daily activities will be assessed by means of a Visual Analogue Scale (VAS).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional study

Study drug and medical condition

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

AZELASTINE HYDROCHLORIDE

FLUTICASONE PROPIONATE

Medical condition to be studied

Rhinitis allergic

Population studied

Short description of the study population

Patients who were getting the same prescription for allergic treatment for the first time in routine clinical practice.

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

Rhinitis allergic patients

Estimated number of subjects

1500

Study design details

Data analysis plan

All variables will be analysed by means of adequate descriptive statistics.

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

Prospective patient-based data collection

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