Profile of patients prescribed Dymista® (azelastine hydrochloride/ fluticasone propionate) nasal spray for allergic rhinitis in the UK

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## Administrative details

EU PAS number	
EUPAS4414	
Study ID	
15022	
DARWIN EU® study	
No	
Study countries	
Denmark	
Germany	
Norway	

#### Study description

Dymista® is a nasal spray containing a mixture of an antihistamine and a corticosteroid, which is approved in the UK for the treatment of allergic rhinitis (AR) (hay fever and year round allergy). Evidence of its efficacy and tolerability obtained during the regulatory clinical development process has been generated within the constraints of randomised clinical trials with tightly defined patient inclusion criteria. However there have been no studies on the use of Dymista® by patients in the real world clinical setting in the UK.The aim of this study is to understand the demographic characteristics, medical and treatment history of the population of patients that have been prescribed Dymista® by UK specialists, in routine NHS secondary/tertiary care environment in order to inform future strategies for the management and treatment of allergic rhinitis. This study is the UK arm of an international, multicentre study being conducted in several countries in Europe with the aim of including 7,000 patients in total. The study will involve collecting data from patients' medical records (patient's clinical characteristics, predominant symptom, reasons for the patient visit and prescribing Dymista® and previous prescribed medications for AR) and completion of a short questionnaire by patients themselves (number of visits by the patient to a healthcareprofessional in the last year, impact of AR on quality of life, presence of eye symptoms and previous treatment history prescribed and self-medication). In the UK, the study will include anonymised codeddata from 200-250 patients recruited from 20 NHS hospital outpatient clinics (Allergy, Immunology, Ear Nose and Throat clinics).

#### **Study status**

Finalised

### Research institutions and networks

### Institutions

University College London Hospitals NHS Foundation Trust

University Hospital of Wales cardiff, Royal Albert
Edward Infirmary Wigan, Royal Victoria Hospital
Belfast, Wrexham Maelor Hospital Wrexham, Royal
Surrey County Hospita Guildford, Royal
Hallamshire Hospital Sheffield, Northern General
Hospital Sheffield, Cumberland Infirmary Carlisle,
North Devon District Hospital Barnstaple, James
Paget University Hospital Great Yarmouth

### Contact details

Study institution contact

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Study contact

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**Primary lead investigator** 

### Glenis Scadding

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 16/07/2013 Actual: 16/07/2013

#### Study start date

Planned: 16/09/2013 Actual: 30/10/2013

### Data analysis start date

Planned: 15/01/2014 Actual: 01/05/2014

#### **Date of final study report**

Planned: 15/02/2014 Actual: 23/09/2014

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

MEDA Pharmaceuticals Ltd

## Regulatory

No

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

Not applicable

# Methodological aspects

# Study type

# Study type list

### **Study topic:**

Human medicinal product

Disease /health condition

### Study type:

Non-interventional study

### Scope of the study:

Drug utilisation

#### **Data collection methods:**

Combined primary data collection and secondary use of data

### Main study objective:

To understand the demographic characteristics, medical and treatment history of the population of patients that have been prescribed Dymista® in routine UK

NHS secondary/tertiary care, in order to inform future strategies for the management and treatment of allergic rhinitis. This information is also thought to be of interest to NHS commissioners, in order to understand the impact on NHS services.

### 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

Rhinitis allergic patients that have been prescribed Dymista® by UK specialists

#### 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

### Special population of interest, other

Rhinitis allergic patients

#### **Estimated number of subjects**

250

### Study design details

#### **Outcomes**

To describe the clinical indications for which Dymista® has been prescribed in UK clinical practice, To describe the: demographic characteristics of patients receiving Dymista® for allergic rhinitis (AR) in UK clinical practice, reasons for prescribing Dymista®, AR symptoms experienced when Dymista® is prescribed, impact of AR on daily patient life at initiation of Dymista®, all previous treatments prescribed for AR, and number of visits to a HCP in the last year, prior to starting Dymista®

### Data analysis plan

Data relating to participating centres in the UK will be descriptive in nature. Both distributions and descriptive statistics of both central tendency (medians and arithmetic or geometric means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables. Nominal variables will be described with frequencies, percentages and modes, while ordinal variables will also have medians and interquartile ranges described. Confidence intervals will be provided for proportions of nominal variables and for means of quantitative variables. Analyses will be performed using the available data. No attempt will be made to impute missing values.

# 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, Routine medical notes

## 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