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

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Study Finalised

Administrative details

EU PAS number

EUPAS4414

Study ID

15022

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Germany
- ☐ Norway

Sweden

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

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:

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

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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

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

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