Assessment of Oralair® use in real-life (EVORA)

First published: 13/05/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49935

EU PAS number

EUPAS9358

Study ID

49935

DARWIN EU® study

No

Study countries

☐ France

Study description

Oralair® is a sublingual immunotherapy tablet indicated for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis with relevant clinical symptoms confirmed by positive skin test and or existence of pollen specific IgE antibodies for any of the five grass species contained in this drug. Oralair® is approved for use in children (older than 5 years of age) and adults. The EVORA study was requested by the French authorities to assess the use of Oralair® in real-life in France. This study is a prospective cohort of 300 adults and 150 children who initiate Oralair® for the next pollen season with a follow-up until the end of the season and is conducted by allergy specialists.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Patrick Blin

Study contact

plateforme.bpe@u-bordeaux.fr

Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/12/2013

Study start date

Planned: 01/12/2014

Actual: 01/12/2014

Date of final study report

Planned: 30/04/2016

Actual: 23/06/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Stallergenes SA

Regulatory

Was the study required by a regulatory body?

Yes

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:

Disease epidemiology

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To describe the prescription patterns of Oralair®: indication, dosage, date of drug initiation compared to pollen season, concomitant drugs including antihistamines, local corticosteroids, cromones, and decongestants

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

GRASS POLLEN ALLERGEN EXTRACT

Anatomical Therapeutic Chemical (ATC) code

(V01AA02) grass pollen

grass pollen

Medical condition to be studied

Rhinitis allergic

Population studied

Short description of the study population

Allergic rhinitis with or without conjunctivitis in children (older than 5 years of age) and adults treated with Oralair® in real-life in France.

Age groups

Children (2 to < 12 years)

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

Patients with allergic rhinitis

Estimated number of subjects

450

Study design details

Data analysis plan

Statistical analysis will be carried out by the Bordeaux pharmacoepi according to a documented and approved Statistical Analysis Plan (SAP). The SAP describes statistical analysis as foreseen at the time of planning study. Statistical analysis will be performed after database lock using SAS® software (SAS Institute, last version, North Carolina, USA). Statistical analysis will be

conducted separately for children and for adults. Qualitative variables (binary or categorical) and ordinal variables will be described in terms of number and frequency. Quantitative variables will be described in terms of number, mean, standard deviation, median and extreme values. The 95% confidence interval will be calculated for the relevant parameters.

Documents

Study publications

Blin P, Demoly P, Drouet M, Falissard B, Lignot-Maleyran S, Maizi H, Lorrain S,...

Data management

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