ALTO, An international non-interventional registry on the quality of life of patients with grass pollen-induced Allergic Rhinitis Treated with Oralair®

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Study Ongoing

Administrative details

EU PAS number

EUPAS6076

Study ID

9749

DARWIN EU® study

No

Study countries

Austria

Belgium

France

Germany
Italy
Netherlands
Russian Federation
Spain
Switzerland

Study description

Results from clinical trials need to be complemented with real-life information on short-, mid- and long-term outcome in patients treated with Oralair®. The purpose of the present study is therefore to describe the patient’s perception of quality of life and effectiveness of Oralair® over a follow-up period of up to 5 years, in real-life settings.This is a five-year international, prospective, observational, multicentre, longitudinal, pharmacoepidemiological study.The study will be conducted in 2 phases:- 1st Phase (Screening visit):During the 2014 grass-pollen season, investigators will consecutively include all patients meeting the selection criteria of the 1st Phase. This 1st phase is meant to collect data during grass-pollen season in patients with allergic rhino-conjunctivitis and without any AIT treatment.- 2nd Phase (Longitudinal Study): Investigators will include in the 2nd Phase of the study all patients of the 1st phase starting a treatment with Oralair® approximately 4 months before the 2015 grass-pollen season. Patients will be followed-up in accordance with the normal course of patient care. Follow-up visits are routinely performed twice a year approximately (depending upon local usual practices).Patients (and/or, in the case of a minor, his/her parents or legally acceptable representatives) will be asked to complete Patient Booklets about treatment compliance, Quality of Life and disease intensity at Screening visit (V0) and at home during each pollen season.

Study status

Ongoing

Research institutions and networks

Institutions

Pr. Alain DIDIER

UZ Gent, Dr. Gevaert Belgium, CHR Namur, Dr. Bradatan Belgium, Hopital Larrey, Toulouse, Dr. Mailhol France, Dr. M. Hoffmann, Witten Germany, Città della Salute Hospital, Torino, Dr. Marengo Italy, Moscow City Hospital N°57, Dr. Novikova Russia, Hospital Virgen de la Vega, Dr. Muñoz Bellido Spain, Luzerner Kantonsspital, Luzern, Dr. Müllner Switzerland

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alain DIDIER

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/11/2013

Actual: 02/12/2013

Study start date
Planned: 01/04/2014

Actual: 19/05/2014

Data analysis start date
Planned: 30/09/2015

Date of interim report, if expected
Planned: 30/09/2016

Date of final study report
Planned: 30/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Stallergenes SA

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Health Related Quality of Life

Main study objective:

The purpose of the present study is to describe patient’s perception of quality of life and effectiveness of Oralair® over a follow-up period of up to 5 years, in real-life settings.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

International, prospective, observational, multicentre, longitudinal, pharmacoepidemiological study

Study drug and medical condition

Medicinal product name, other

ORALAIR*31CPR SUBL 100IR-300IR

Medical condition to be studied

Rhinitis allergic

Population studied

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)

Estimated number of subjects

2500

Study design details

Outcomes

Change of the health related generic and disease specific Quality of Lifemeasured during the grass-pollen seasons. - Disease intensity according to the Visual Analogic Scale (VAS)- Effectiveness of Oralair® in allergic rhinitis management- Patient compliance to Oralair®- Socio-economic impact of Oralair® (physician visits, hospitalizations,sick-leaves related to allergic rhinitis)

Data analysis plan

Analysis of the primary and secondary objectives will be performed on the Study Population. Change from Screening visit will be calculated and described at each time point of the 2nd phase of the study: -scores of 7 domains (Activity limitation, Sleep problems, Nose symptoms, Eye symptoms, Non-nose/eye symptoms, Practical problems and Emotional function) and the overall score of the RQLQ(S)+12 will be described,-scores of the 8 dimensions (Physical functioning, Role-physical limitations, Bodily pain, General health, Vitality, Mental health, Role-emotional limitations, Social functioning) of the SF-12 v.2 / SF10 v.2 will be described,-the perception of disease intensity (VAS) will be described,-effectiveness of Oralair in allergic rhinitis management will be described,-patient compliance to Oralair will be described for each year of the treatment period,-medical resources use will be described for each year of the whole study period.

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 source(s), other

European Aeroallergen Network Austria

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