EVORA - Evaluation of Oralair® in real conditions of use

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General

Identification

Detailed name	Evaluation of Oralair® in real conditions of use
Sign or acronym	EVORA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS n°14.514 - CNIL n°914403

General Aspects

Medical area	General practice Otolaryngology or ENT Pediatrics Pneumology Study of allergies
Pathology (details)	Allergic rhinitis with or without conjunctivitis with grass pollen
Health determinants	Lifestyle and behavior Medicine
Keywords	Bordeaux PharmacoEpi Platform, Grass pollen, Adults and children, Prospective cohort, Allergic rhinitis with or without conjunctivitis, Oralair, Department of Medical Pharmacology

Scientific investigator(s) (Contact)

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Organization	Université de Bordeaux

Collaborations

Funding

Funding status	Private
Details	LABORATOIRE STALLERGENES

Governance of the database

Sponsor(s) or organisation(s) responsible	Universite de Bordeaux - Plateforme Bordeaux PharmacoEpi - Service de pharmacologie médicale - CIC Bordeaux CIC1401
Organisation status	Public
Presence of scientific or steering committees	Yes
Labelling and database evaluation	Quality control of the data entered (internal control)

Additional contact

Main features

Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	An administrative base or a register
Base or register (detail)	List of health-care professionals qualified in allergology via CEGEDIM
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Patients (adults and children from 5 years of age) were prospectively included between November 2014 and February 2015 by participating physicians specialising in allergology.
Database objective	
Main objective	Describe the prescription details of Oralair®: indication, dosage, date of introduction of the treatment with respect to the pollen season, concomitant treatments, in particular antihistamines, local corticosteroids, cromones and decongestants.
Inclusion criteria	Patient initiating a treatment with Oralair® for the next pollen season, Patient not previously treated with Oralair®. Exclusion criteria: Refusal to participate, Patient not living in the area or expected to move during the study period, Patient with a language barrier (unable to read the newsletter or complete self-questionnaires) Patient participating in a therapeutic clinical trial
Population type	
Age	Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)

	Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	X - Diseases of the respiratory system
Gender	Male Woman
Geography area	National
Detail of the geography area	Physicians in either private and hospital practice or both with an allergology activity in France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2014
Date of last collection (YYYY or MM/YYYY)	2015
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	525 patients (311 adults and 214 children)
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	General characteristics of the patient (sex, age, comorbidities, treatments) - Results of assays/tests and symptomatology of allergic rhinitis
Declarative data (detail)	Paper self-questionnaire Phone interview
Details of collected declarative	Collection of the perception of the symptoms of

data	allergic rhinitis on quality of life before and after use of the treatment
Biological data (detail)	Specific IgE assay results for grass pollen
Administrative data (detail)	Surname, first name, phone number and e-mail address
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medical/paramedical consultation Medicines consumption
Quality of life/perceived health (detail)	Treatment outcome score (positive or negative benefit) from self-evaluation questionnaires of the symptoms on quality-of-life completed by patients

Procedures

Data collection method	The study data is collected through standardised paper questionnaires completed by participating physicians and standardised self-questionnaires completed by patients. The data is then entered into a specific study database
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.) Monitoring by contact with the referring doctor
Details on monitoring of participants	After the inclusion consultation, participating physicians were asked to complete an end-of-study questionnaire at the end of the pollen season (by September 2015) for each patient included and monitored. For patients not seen by physicians, the questionnaire was completed directly with the patient during a telephone interview conducted by the clinical research associates of the coordinating Centre.
Links to administrative sources	Yes
Linked administrative sources (detail)	The population included and monitored in the study was compared with the EGB population

Promotion and access

Promotion

Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Ownership of and access to the study data were the subject of an agreement between the Université de Bordeaux and the laboratory. The terms of access to the database must be established by a request to the study's scientific advisory board.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only