Study on feeling according to the patient of allergens specially prepared for individuals (allergenic ‘Named Patient Products’ NPPs) (ERAPP)

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Study Ongoing

Administrative details

EU PAS number

EUPAS36947

Study ID

40873

DARWIN EU® study

No

Study countries

France

Study description

In France, allergenic NPPs are named APSI for “Allergènes Préparés Spécialement pour un Individu” (allergens specially prepared for an individual). NPPs are indicated in allergen specific immunotherapy for respiratory tract disorders, allergic rhinitis and/or allergic asthma. This study is carried out as part of the evaluation of sublingual allergenic NPPs planned in 2023 by the French agency in charge of health technology assessment: the Haute Autorité de Santé (HAS). With this non-interventional study, real-world data will be gathered to evaluate the impact of a sublingual immunotherapy by NPPs during a 15-month follow-up period in terms of patient feeling, symptom evolution, sleep and quality of life. NPPs compliance as well as the patient healthcare use in relation to allergy will also be assessed. Analyzes will be performed separately for children and teenagers/adults, according to the sublingual immunotherapy duration. Linkage of data collected through a patient questionnaire to data from the French nationwide healthcare system database (SNDS database) could be performed with the patient agreement, according to the new procedure defined by the French law, provided that additional funding are granted.

Study status

Ongoing

Research institutions and networks

Institutions

University of Bordeaux

France

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Institution | Educational Institution

Société Française d'Allergologie France

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/12/2019

Study start date

Planned: 01/09/2020

Actual: 01/09/2020

Data analysis start date
Planned: 01/10/2021

Date of interim report, if expected
Planned: 30/06/2023

Date of final study report
Planned: 30/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ALK, Stallergenes Greer

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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To evaluate the impact of an allergen sublingual immunotherapy by NPPs in terms of patient feeling in relation to his allergy during a 15-month follow-up period, according to the duration of the sublingual immunotherapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ALLERGEN EXTRACT

Medical condition to be studied

Allergic respiratory disease

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 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

80.000

Study design details

Outcomes

Evolution of patient feeling in relation to his allergy during a 15-month follow-up period. Symptom evolution (questionnaires ARIA, T5SS, GINA), sleep evolution (questionnaire Epworth), NPPs compliance, quality of life evolution, evolution of healthcare use in relation to allergy during a 15 months follow-up period.

Data analysis plan

Statistical analyses will be carried out by the Bordeaux PharmacoEpi platform. Analyses will be conducted separately for children and teenagers/adults and performed according to the sublingual immunotherapy duration:- A flow chart depicting the number of patients enrolled and followed,- Description of patients and comparison of their characteristics according to the sublingual immunotherapy duration,- Assessment of treatment impact score during the follow-up,- Proportion of patients with a treatment benefit,- Description of symptoms at inclusion and evolution during the follow-up, for allergic rhinitis and asthma, - Sleep, quality of life and NPPs compliance evolution during follow-

up,- Description of the 15-month healthcare resources use (SNDS data),- Assessment of disease score with SNDS data during historic period.Two last analyses will be performed according to the procedure defined by the French law, provided that additional funding are granted.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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