A non-interventional observational retrospective study for the study of the risk factors associated to the related to treatment adverse events occurred by the administration of allergen specific immunotherapy administered by sublingual route (ALK-SLI-2013-01)

First published: 10/03/2014

Last updated: 27/02/2019

Study Finalised

Administrative details

EU PAS number

EUPAS6012

Study ID

28562

DARWIN EU® study

No

Study countries

Spain

Study description

A non-interventional, observational, retrospective, multi-centre, open-label study. The study will include 20 investigators with 10 patients each into the study. Overall, there are 200 patients to be included.

Study status

Finalised

Research institutions and networks

Institutions

NA

Contact details

Study institution contact

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Study contact

amoralgregorio@gmail.com

Primary lead investigator

Angel Moral de Gregorio

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/04/2014

Actual: 01/01/2014

Study start date
Planned: 01/05/2014

Actual: 18/03/2014

Data analysis start date
Planned: 01/09/2014

Actual: 18/02/2015

Date of final study report
Actual: 18/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ALK- Abello

Study protocol

RF SLIT V2.0 25 NOV 2013_JP.pdf (698.08 KB)

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:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To try of determining, in a real-life setting, the possible risk factors –associated to the patients or to the allergen extract- that may influence on the appearance

of related to treatment adverse events occurred by the administration of SLIToneULTRA®.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A non-interventional, observational, retrospective, multi-centre, open-label study

Population studied

Short description of the study population

1. Patients diagnosed of allergic rhinoconjunctivitis with/without mild to moderate allergic asthma by allergic sensitization to: grass, Olea, or House Dust Mites (D. pteronyssinus/D. farinae)
2. Allergic sensitization diagnosed by cutaneous test (skin pricktest _SPT-) and/or specific IgE according to the common clinical routine of each investigator.
3. Patients treated with SLIToneULTRA® for at least 3 months previously to his/her inclusion in the study
4. Patients able to understand and answer on his/her own the questionnaires used in the study
5. Patients above 5 years of age, according to the clinical routine of each investigator
6. Patients that give their consent in writing to participate in the study. In case

of patients between 12-17 years old the representative’s consent should accompany the own patient’s consent and in patients < 12 years old the consent will be obtained from the patient representative.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Estimated number of subjects

200

Study design details

Outcomes

Incidence of eventsadverse, Adherence to the treatment through the Morisky-Green questionnaire and satisfaction through the SATMED-Q questionnaire

Data analysis plan

A descriptive analysis for all data collected will be held in the CRD.

Documents

Study publications

Moral A, Moreno V, Girón F, El-Qutob D, Moure JD, Alcántara M, Padial A, Oehlin…

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 sources (types)

Spontaneous reports of suspected adverse drug reactions

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