# 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

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**Study start date**
Planned: 01/05/2014

Actual: 18/03/2014

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**Data analysis start date**
Planned: 01/09/2014

Actual: 18/02/2015

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**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

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**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