

# A non-interventional observational study assessing the safety and tolerability of ACARIZAX® in adults (18-65 years of age) (RELIEF)

**First published:** 19/10/2021

**Last updated:** 23/04/2024

Study

Planned

## Administrative details

### EU PAS number

EUPAS43753

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### Study ID

43754

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### DARWIN EU® study

No

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### Study countries

 Netherlands

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### Study description

ACARIZAX® has been approved by the Dutch regulatory authorities in August 2016 for treatment of allergic rhinoconjunctivitis caused by housedustmites. This non-interventional study in adults is conducted in order to obtain information of use of ACARIZAX® in a real life setting. The number of patients to be included in the study will add to the existing safety data for the product. So far Dutch physicians don't have any experience with use of ACARIZAX®. This study will gain initial experience with this new treatment under routine conditions of everyday practice. Primary objective: To investigate the safety and tolerability of ACARIZAX® in adults. Non-interventional, observational, multi-centric, open-label study. Study design: A total number of 3 visits is planned during the study and a phone contact approximately 1 week after first administration Study population: Adult patients treated with Acarizax according to standard practise (SmPC Acarizax) for their allergic rhinitis and/or conjunctivitis. Assessments: Adverse Events (AE)/ Adverse Drug Reactions (ADR)/ Serious Adverse Events (SAE), Patient's satisfaction/Convenience and Compliance.

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### **Study status**

Planned

## Research institutions and networks

### Institutions


[ALK-Abelló](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## University Medical Center Utrecht (UMCU)

 Netherlands

**First published:** 24/11/2021

**Last updated:** 22/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

Jeroen Bosch Ziekenhuis, Henri Dunantweg 1, Den Bosch, The Netherlandsweg Department of Allergology, University Medical Center Utrecht, Heidelberglaan 100, Utrecht, The Netherlands

## Contact details

### Study institution contact

Anton Antonakoudis [AANNL@ALK.NET](mailto:AANNL@ALK.NET)

Study contact

[AANNL@ALK.NET](mailto:AANNL@ALK.NET)

### Primary lead investigator

Zana Tempels

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 02/10/2017

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### **Study start date**

Planned: 03/04/2017

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### **Data analysis start date**

Planned: 03/06/2019

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### **Date of final study report**

Planned: 13/10/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ALK-Abello BV

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Other

**If 'other', further details on the scope of the study**

Satisfaction, convenience, compliance and therapeutic effect

**Main study objective:**

collecting safety data of Itulazax in daily practise in patients aged 18-65 years of age.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational, multi-centric, open-label study

## Study drug and medical condition

**Medicinal product name, other**

Itulazax

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**Medical condition to be studied**

Conjunctivitis allergic

Seasonal allergy

## Population studied

**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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**Estimated number of subjects**

400

## Study design details

**Outcomes**

number, kind (MedDRA coding) and assessment of adverse events reported. Per protocol patient and physician satisfaction were asked at end of study or if patient stopped early. estimation by physician of patient compliance at each visit. Control of Allergic Rhinitis and Asthma Test (CARAT score) a measure of disease control and thus of therapeutic effect was also asked at each visit.

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### **Data analysis plan**

Demographics and other baseline characteristics will be displayed with summary statistics (i.e. number of patients, minimum, maximum, mean, median, 25% and 75% percentiles) and frequency tables for categorical variables. AEs as well as breakdown of AEs according to seriousness, severity and causality will be summarised for all AEs and for AEs during administration. AEs will be summarised by system organ class and preferred term and displaying number of patients and frequency of patients having AEs as well as number of AEs. Other statistics will be summarised as well.

## 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)**

## Other

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### **Data sources (types), other**

This is a prospective observational study with written informed consent. sources are the medical records of patients to the extend relevant for the study. The relevant data are entered in an eCRF. Multiple sources therefore.

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No