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

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Last updated: 23/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS43753

Study ID

43754

DARWIN EU® study

No

Study countries

☐ Netherlands

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.

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

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

Zana Tempels

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/10/2017

Study start date
Planned: 03/04/2017

Data analysis start date
Planned: 03/06/2019

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

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:

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

Non-interventional study design, other

Observational, multi-centric, open-label study

Study drug and medical condition

Medicinal product name, other

Itulazax

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)

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.

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No