ITULAZAX Post Authorization Safety (IPAS) Study: A prospective, non-interventional study assessing the safety and tolerability of ITULAZAX in adults with tree pollen allergy in real-life practice (IPAS Study)

First published: 19/09/2019

Last updated: 22/02/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49339

EU PAS number

EUPAS31470

Study ID

49339

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] Germany
- [ ] Netherlands
- [ ] Norway
- [ ] Sweden

Study description

Non-interventional, observational, multi-site, open-label multi-national PASS to investigate the safety and tolerability of ITULAZAX in adult patients in a real-life setting in Germany, the Netherlands, Denmark, Sweden, Norway and Finland.

Study status

Finalised

Research institutions and networks

Institutions

ALK-Abelló

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 178 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Oliver Pfaar

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 10/09/2019

Actual: 18/02/2020

Study start date

Planned: 30/11/2019

Actual: 22/04/2020

Data analysis start date

Planned: 30/09/2022

Actual: 16/01/2023

Date of final study report
Planned: 30/06/2023

Actual: 09/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ALK-Abelló Arzneimittel GmbH

Study protocol

190910-NIS-PASS-ITULAZAX Final Protocol version 1.0.pdf(262.52 KB)

20220811-NIS-PASS-ITULAZAX Final Protocol version 4.0_04102022_update sponsor address.pdf(426.86 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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To investigate the safety and tolerability of the ITULAZAX in adults (18-65 years of age) in the first 4-6 months of treatment in a real-life setting.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational, multi-site, open-label multinational PASS

Study drug and medical condition

Name of medicine, other

ITULAZAX

Medical condition to be studied

Rhinitis allergic

Population studied

Short description of the study population

Adults patients aged 18-65 years old who were prescribed with ITULAZAX in a real-life setting in Germany, the Netherlands, Denmark, Sweden, Norway and Finland.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Patients with allergies

Estimated number of subjects

1000

Study design details

Outcomes

Sum of pre-specified local adverse drug reactions (including lip swelling/oedema, mouth oedema, palatal oedema, swollen tongue/oedema, oropharyngeal swelling (oedema, pharyngeal oedema/throat tightness), laryngeal oedema), Number of treatment related AEs • Number of systemic reactions • Number of non-local adverse drug reactions • Number of serious AEs (SAEs) • Sum of pre-specified local adverse reactions (as specified in the primary endpoint) within the first 4 months of treatment in patients with history of Pollen Food Syndrome (PFS) • Adherence to the first 4 months of treatment.

Data analysis plan

AEs as well as breakdown of AEs and treatment-related AEs (possibly related) according to seriousness, severity and causality will be summarised for AEs during administration (V1 to V4). AEs will be summarised by MedDRA System Organ Classes and MedDRA Preferred Terms displaying number of patients, frequency of patients having AEs as well as number of AEs.

Documents

Study results

2023-06-09_NI-TT-01_Overall Study Report ITULAZAX_Synopsis_Final version.pdf(223.86 KB)

Data management

Data sources

Data sources (types)

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