Study of the safety and tolerability of STALORAL® Birch and STALORAL® Birch/Alder/Hazel with a maximum dose of 300 IR daily in routine application in adults (GO FOR 300)

First published: 27/09/2021

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS43255

Study ID

43256

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Switzerland

Study description

International, prospective, open-label, multicentric, non-interventional Post Authorization Safety Study (PASS) in adults to further describe the safety and tolerability of STALORAL® Birch and STALORAL® Birch/Alder/Hazel at a maximum dose of 300 IR/daily in routine practice.

Study status

Ongoing

Research institutions and networks

Institutions

Stallergenes

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Institution

Contact details

Study institution contact

Medical Department Stallergenes GmbH
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Study contact

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Primary lead investigator

Medical Department Stallergenes GmbH

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/07/2020

Actual: 22/07/2020

Study start date
Planned: 15/09/2020

Actual: 19/10/2020

Data analysis start date
Planned: 15/01/2023

Date of final study report
Planned: 30/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Stallergenes GmbH

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

Effectiveness study (incl. comparative)

Main study objective:

To further describe the safety and tolerability of STALORAL® Birch and STALORAL® Birch/Alder/Hazel at a maximum dose of 300 IR/daily in routine practice in adults suffering from allergic rhinitis, conjunctivitis or rhinoconjunctivitis induced by tree pollen.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V01AA05) tree pollen

tree pollen

Medical condition to be studied

Rhinitis allergic

Conjunctivitis allergic

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

450

Study design details

Outcomes

All adverse events (AEs) that occur on or after the day of first intake of the medicinal product and up to the end of the observation period. Effect of the treatment on the allergic symptoms and on the use of symptomatic medication, patient’s well-being

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Data analysis plan

An overall summary of all AEs, including the number of events and the number and percentage of patients with AEs is drawn up. AEs are summarised on the basis of MedDRA SOC and PT. Further tabular summaries are compiled for SAEs, ADRs (events with a possible causal relationship with STALORAL® Birch or STALORAL® Birch/Alder/Hazel), SADRs, ADRs by severity, ADRs leading to withdrawal from the study, ADRs during the initiation phase (dose escalation phase) or during the course of the treatment (maintenance phase), ADRs requiring medical treatment and ADRs or situations of special interest. Also analysed are the time to occurrence of the ADRs (time interval from the last administration of STALORAL® Birch or STALORAL® Birch/Alder/Hazel), duration and time course of the ADRs. The statistical evaluation of further outcomes takes place descriptively.

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

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