Exploring the effectiveness of Itulazax on birch-related food allergy in adults treated with Itulazax for birch pollen allergy

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The primary aim of this study is to investigate whether sublingual treepollen immunotherapy with Itulazax has an effect on food allergy-related quality of life in adults with tree pollen allergic rhinitis who also have a food allergy in the context...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON53964

Source
ToetsingOnline

Brief title
ItulaFAR

Condition

- Allergic conditions

Synonym
pollen-food-syndrome, treepollen related food allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pollen-food-syndroom, Quality of life, SLIT, Sublingual immunotherapy birchpollen

Outcome measures

Primary outcome

Does the use of Itulazax 12 SQ-Bet lyophilisate (a sublingual tree pollen immunotherapy) in adults with allergic rhinitis and paraberk syndrome affect the pollen-food-syndrome?

Primary outcome measure

In patients treated for allergic rhinitis with Itulazax who also have pollen-food-syndrome, what is the effect on food allergy-related quality of life at 1 and 3 years relative to baseline as measured by the Food Allergy Quality of Life Questionnaire - Adult Form (FAQLQ-AF).

Secondary outcome

o In patients treated with Itulazax for allergic rhinitis who also have pollen-food-syndrome, what is the effect on:

- The threshold of food allergy
- Severity of food allergy
- Time that the complaints persist
- Height of specific IgE
- Size of skin reaction after skin test
- Possibility of ingestion of fresh/raw products in the context of pollen-food-syndrome that previously gave complaints

- The basophil activation test (BAT) in hazelnut-allergic patients

o Which factors (including demographic factors, skin test, sIgE in blood, severity of food allergy, type of food) are related to a good effect of Itulazax on pollen-food-syndrome?

o Does the patient's expectation of the effect of Itulazax on food allergy symptoms influence the primary and secondary outcome measures?

Study description

Background summary

Pollen from the birchtree, as well as other related trees of the Betulaceae and Fagaceae family, are the most dominant treepollen in Northern and Central Europe and cause a wide range of allergic complaints such as rhinitis and asthmatic symptoms (T. Biedermann, et. al. , 2019). In the general European population, the prevalence of birch pollen sensitization ranges from about 8% to 16%. Several European data indicate that birch pollen are responsible for a large percentage of sensitization among tree-allergic patients in Europe, with Bet v 1 as the main allergen (T. Biedermann, et. al., 2019).

In addition to rhinitis and asthmatic symptoms, patients with a birch pollen allergy also frequently experience IgE-mediated food allergies. These reactions are caused by IgE cross-reactivity between the birch pollen allergen Bet v 1 and its homologues in foods and is also known as pollen-food-syndrome. About 70% of birch pollen-allergic patients have allergic complaints to various foods (usually fruits, vegetables and nuts) in the context of such a pollen-food-syndrome (M. Geroldinger-Simic, et. al., 2011 ; N. Eriksson, et al., 1982).

Symptoms of pollen-food-syndrome mainly consist of mild local reactions such as itching and/or tingling of the lips, tongue and/or throat. More serious complaints such as swelling of the throat may occur. In addition, patients may also experience systemic reactions such as urticaria, rhinitis or anaphylaxis. Although it can generally be assumed that severe systemic reactions occur less frequently in pollen-related food allergies, it should be borne in mind that

they do occur (J. Klein-Tebbe, et. al., 2002). Because the allergens that cause the pollen-related food allergy are labile proteins, which are not resistant to heating, for example, processed (e.g. cooked) foods cause fewer complaints than raw foods.

At the Allergology outpatient clinic in the UMC Utrecht, patients with allergic rhinitis to tree pollen are noted to also have food allergies, especially to fruit, vegetables and/or nuts. What is striking is that some patients who receive immunotherapy for birch pollen, eventually experience fewer complaints from certain foods. Both during and after the therapy it has been noted that some patients can eat these products again without any complaints.

Study objective

The primary aim of this study is to investigate whether sublingual treepollen immunotherapy with Itulazax has an effect on food allergy-related quality of life in adults with tree pollen allergic rhinitis who also have a food allergy in the context of pollen-food-syndrome.

The secondary aim of this study is to investigate whether treatment with Itulazax in this patient group has an effect on the severity and threshold of food allergy, tolerance to raw foods, level of specific IgE and size of the skin test.

Study design

Prospective cohort study assessing whether the use of Itulazax in adults with allergic rhinitis has an effect on food-allergic complaints in the context of pollen-food-syndrome in the outpatient clinic of UMC Utrecht. The Itulazax will be prescribed in routine care to patients with allergic rhinitis to tree pollen who qualify according to the current guideline.

Inclusion of patients will take place in 2022 to 2024. The minimum follow-up period for patients is 3 years after the start of the study, so it runs until at least 2027.

Study burden and risks

The treatment with Itulazax will most likely have a positive effect on the patient's hay fever symptoms with the tree pollen, which is also the reason why this treatment has been prescribed (in the context of regular care). Itulazax could also have a positive effect on food allergy symptoms, but this is not certain. That is why this research is being conducted.
If the patient participates in this study, insight is provided into the course of the food-allergic complaints at the time of treatment with Itulazax. This drug could possibly be given in the future as a treatment for patients with

pollen-food-syndrome.
The burden of the research do not outweigh the positive effects of the therapy with Itulazax.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Adults (18 years or older) with allergic rhinitis for treepollen who will start with Itulazax (SLIT treepollen).
- Pollen-food synrome for at least one of the cross-related allergens with birchpollen (bet v1) and sensibilisation in skinpricktesting or ImmunoCAP.
- The abbility to sign informed consent.

Exclusion criteria

- Patients with allergic rhinitis without treepollensensibilisation.
- Patients with allergic rhinitis, but without food allergy.
- Patients with a contraindication for Itulazax (due to the SMPC)
- Patients younger <18 years, of > 65 years
- Patients with chronic spontaneous urticaria and/or chronic spontaneous angiooedema.
- Patients who do not speak the Dutch language.
- Patients who do not want or are able to sign the informed consent
- Patient with previous treatment of subcutaneous immunotherapy birchpollen in the last 3 years.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-03-2023
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	11-11-2022
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	22-03-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82129.041.22