A dose-response evaluation of ALK tree allergy immunotherapy tablet

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The aim is to investigate whether a melting tablet that contains birch pollen allergen will decrease the hay fever symptoms and may alleviate the need for conventional allergy symptom-suppressing medication. The purpose of this specific study is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON39055

Source
ToetsingOnline

Brief title
TT-02 study

Condition

- Allergic conditions

Synonym
hayfever, tree allergy

Research involving
Human

Sponsors and support

Primary sponsor: ALK B.V.
Source(s) of monetary or material Support: sponsor

Intervention

Keyword: hayfever, immunotherapy tablet, tree allergy

Outcome measures

Primary outcome

The average daily rhinoconjunctivitis symptom score during the entire BPS

Secondary outcome

The average rhinoconjunctivitis daily medication score (DMS) during the BPS

The combined rhinoconjunctivitis symptom and medication score during the entire BPS.

The average rhinoconjunctivitis DSS, average rhinoconjunctivitis DMS and average rhinoconjunctivitis DCS during the entire TPS (hazel, alder and birch)

Well days/symptom and medication free days/Days with severe symptoms in the entire BPS and the entire TPS

The average daily asthma symptom score during the entire BPS and the entire TPS

Global evaluation in an overall comparison of this BPS compared to the previous BPS

Study description

Background summary

Allergy vaccination or specific immunotherapy is the practice of giving specific allergens to a person who is allergic to that particular allergen. When given regular doses of the allergen, the body*s tolerance toward the allergen increases and you will experience fewer or no symptoms.
Allergy vaccines are normally given as injections under the skin or as drops or tablets applied under the tongue.
In this trial the trial medication is a dispersible tablet, which means the tablet will quickly melt and be absorbed by the mucous membrane when placed

under the tongue

Study objective

The aim is to investigate whether a melting tablet that contains birch pollen allergen will decrease the hay fever symptoms and may alleviate the need for conventional allergy symptom-suppressing medication. The purpose of this specific study is finding the right dose, but also finding the best balance between safety and efficacy of the tablet. ALK the tablet has been studied in a previous clinical study.

Study design

Randomized double blind placebo study in different centers and different countries with 6 different doses of birch pollen vaccine tablet being compared with a placebo tablet (dummy tablet which no active / active substance). The study will last 6 to 10 months while the participants will visit the clinic several times for study-related tests

Intervention

Study medication and laboratory assessments

Study burden and risks

Patients may experience side effects from the use of study medication, the most common side effect of birch pollen allergy tablet are local reactions suchas tingling in the mouth. Most of these side effects / symptoms are mild to moderate and usually go on after 30 minutes. A list of the most common complaints from previous studies is described in the ICF.

Blood samples can cause mild pain, redness, bruising and / or irritation at the place where blood has been drawn.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Written informed consent obtained before entering the trial
2. Male or female aged 18-65 years
3. A documented clinically relevant history of birch pollen induced allergic rhinoconjunctivitis (with or without asthma), with uncontrolled symptoms despite having received symptomatic drug treatment during the birch pollen seasons 2011 and 2012
4. An appropriate minimum level of birch pollen allergic rhinoconjunctivitis symptoms corresponding to moderate to severe, defined as a total DSS score of (retrospective) score of at least >=8 on the worst day in the previous birch pollen season (e.g. 2 (on a scale from 0 to 3) on at least 4 out of 6 symptoms (4 nasal and 2 eye symptoms))
5. Having experienced at least one of the following, due to allergic rhinoconjunctivitis during the previous birch pollen season: sleep disturbance, impairment of daily activities, leisure and/or sport, impairment of school or work, or troublesome symptoms
6. Positive SPT response (wheal diameter >= 3 mm larger than the negative control) to Betula verrucosa
7. Positive specific IgE against Bet v 1 (>= IgE Class 2; >=0.70 kU/L) at screening
8. Female subjects, who are fertile must have a negative pregnancy test and be willing to practise appropriate contraceptive methods until the end of trial
9. Subjects must be willing and able to comply with trial protocol regimens.

Exclusion criteria

1. A clinically relevant history of symptomatic seasonal allergic rhinitis and/or asthma, having received regular medication, due to another allergen source than birch, hazel, and alder,

overlapping the birch pollen season
2. A clinically relevant history of perennial allergic rhinitis and/or asthma having received regular medication due to an allergen to which the subject is regularly exposed
3. A clinical history of uncontrolled asthma within 3 months prior to screening
4. Reduced lung function, defined as FEV1 < 70% of predicted value after adequate pharmacologic treatment
5. Previous treatment with immunotherapy with birch pollen allergen (or a cross-reacting allergen (hazel or alder):
a.For immunotherapy without updosing phase: for more than 1 month within the last 5 years
b.For immunotherapy with an updosing phase: treatment which has reached maintenance dose (permitted if discontinued before reaching maintenance)
6. Ongoing immunotherapy with any specific immunotherapy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ALK tree AIT
Generic name:	NA

Ethics review

Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-06-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-06-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-10-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-11-2012
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-04-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-04-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	21-05-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EudraCT	EUCTR2012-000031-59-NL
CCMO	NL40557.056.12