Twin SUBLIVAC® Grasses Clinical Efficay Study

Published: 15-05-2006
Last updated: 14-05-2024

To show that treatment with SUBLIVAC® Grasses is clinically effective by means of reduction in allergic symptoms and/or use of allergic symptomatic medication in subjects suffering from IgE mediated allergic complaints triggered by grass pollen.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON30665

Source
ToetsingOnline

Brief title
niet van toepassing

Condition

- Autoimmune disorders

Synonym
hayfever, IgE mediated allergic disorders triggered by grass pollen

Research involving
Human

Sponsors and support

Primary sponsor: HAL Allergenen Lab
Source(s) of monetary or material Support: HAL Allergy BV

Intervention

Keyword: Allergy, grasses, immunotherapy, placebo, rhinitis

Outcome measures

Primary outcome

This effect will be primarily measured by means of the clinical index score (a combination of symptom score and use of medication). When the mean CIS in the SUBLIVAC® Grasses group is a minimum of 30% lower than the mean CIS from the placebo group, SUBLIVAC® Grasses is considered clinically effective. A minimal reduction in symptoms of 30% is considered clinically relevant according to the Malling criterion.

Secondary outcome

Secondary parameters include CIS derived variables.

Secondary objectives are to determine if a deviation in mast-cell serum tryptase level at screening is predictive for the occurrence of adverse reactions to IT and/or (lack of) efficacy and if a present oral allergy syndrome improves through SUBLIVAC® Grasses therapy.

With the 'rhinoconjunctivitis quality of life questionnaire" it is expected that the SUBLIVAC® Grasses treated patients score better than the placebo group.

With the quantitative skin prick test it is expected that the SUBLIVAC® Grasses treated patients will react less sensitive than the placebo treated patients.

IgG is determined sinceit is considered an indicator for the efficacy.

Study description

Background summary

Allergen specific immunotherapy is the only causial treament of IgE mediated allergies. Sublingual treatment is especially considered patient friendly alsoe because of the low incidence and mostly mild side effects. Ifficacy od specific immunotharpy has been prooven in multiple double-blind, placeobo controlled clinical studies.

Sublivac is a sublingual allergen extract which has been marketed since 1997. Sublivac is indicated for the treatment of allergic rhinitis, allergic conjuntivitis and allergic astma caused by allergens from e.g. house dust mite and grasspollen. Diagnosis needs to be confirmed by skin prick test or specific serum IgE test (RAST). Sublivac is intended for treatment of both adults as well as children of five years and above. So far, Sublivac has been produced patient specific.

In this study it will be determined if Sublivac Grasses can reduce symtpoms and/or use of symptomatic medication and is safe to use. Sublivac grassen consists of allergen extract of Lolium perenne, Phleum pratense en Poa pratensis pollen.

Study objective

To show that treatment with SUBLIVAC® Grasses is clinically effective by means of reduction in allergic symptoms and/or use of allergic symptomatic medication in subjects suffering from IgE mediated allergic complaints triggered by grass pollen.

Study design

Double-blind, block randomised, placebo-controlled, multi-centre, international, parallel groups.

Intervention

Start with two drops daily of SUBLIVAC® Grasses 10.00 AU/ml or placebo and increase by two drops daily, until the maintenance dose of 10 drops SUBLIVAC® Grasses is reached.

Study burden and risks

Some subjects developed local side effects, mostly within the first few days after starting with sublingual immunotherapy, such as itching and swelling of the oral mucous membrane. These side effects mostly resolve quickly and without further treatment. Also mild systemic reactions might occur like itching eyes, sneezing, coughing and worsening of atopic eczema. Diarrhea and abdominal pain

might occur some time after medication in take. Intensified systemic reactions (shortness of breath, generalized urticaria and Quincke*s Oedema) might also occur. Life-threatening side effects have never been reported with the sublingual immunotherapy we will use in this study.

The extra burden for the aptients consists ofapproximately four extra visits and:
2x rhinoconjunctivitis questionnaire
During the first two week of therapy a daily diary concerning medication intake and side effects.
During the three moneths of the pollen season a daily diary on allergy symptoms and medication use.
9x examination of eyes, nose and mouth
1x skin prick test series
2x quantitative skin prick test
1x collection of two tubes blood
2x collection of three tubes blood

The results of this study are needed to find out if and after how long SUBLIVAC® Grasses can reduce allergy symptoms and/or the use of anti-allergy medication. This information will benefit other patients with a grass pollen allergy so they will receive medication which effectively reduces allergy symptoms or the use of anti-allergy medication.

The benefit for you is that you receive three years of immunotherapy and antihistaminics treatment during the study free-of-charge. Visits to the doctor during the study will not be charged and the patient will receive a travel cost reimbursement of ¤ 25 per visit. For the visits when a quantitative skin prick is done, an extra ¤ 25 reimbursement will be given for the inconvenience.

Given the low risk, low (time)burden and the offer of oral antihistamines during the pollen season inclusion of patients in this study is justified.

Contacts

Public
HAL Allergenen Lab

Parklaan 125
2011 KT Haarlem
Nederland
Scientific
HAL Allergenen Lab

Parklaan 125
2011 KT Haarlem
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects with allergic rhinoconjunctivitis with or without mild asthma (FEV1 >= 70%) for at least 2 years. Their allergic symptoms should be related to grass pollen
Use of anti-allergy symptomatic medication in the last pollen season (or, in case of a low pollen season, in one of the two previous years)
A positive skin prick test (>3 mm) for grasses and specific serum IgE-test
(>1 U/ml) for grass pollen (Lolium perenne, Phleum pratense and Poa pratensis).
Age 12 years or older.
Subjects (and their parents if required) shall give a written informed consent

Exclusion criteria

A positive SPT for perennial allergens of house dust mite
Symptoms related to concomitant sensitisation to perennial allergens of pets
Chronic asthma or emphysema, particularly with a FEV1 < 70 % of predicted value or use of inhalation corticosteroids outside grass and tree pollen season for more than two episodes and/or longer than fourteen days
Use of symptomatic medication for more than three episodes and/or longer than three days outside the tree- or grasspollen season
Serious immuno-pathological diseases or malignancies (including auto-immune diseases, tuberculosis, HIV)
Inflammation and infection of the target organ

Severe atopic dermatitis requiring systemic immuno-suppressive medication
Allergen specific immuno-therapy treatment within the last 5 years for a period longer than three months

Study design

Design

Study phase:	3
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):	21-11-2006
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sublivac Grasses 10.000 AU/ml
Generic name:	not applicable

Ethics review

Approved WMO

Date:	15-05-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	21-07-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2006
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-11-2006
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-07-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-08-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-08-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-08-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2005-005175-16-NL
CCMO	NL12128.100.06