Sublingual immunotherapy (SLIT) with grass pollen allergen for grasspollen induced rhinoconjunctivitis in children.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23382

Source
NTR

Brief title
STARDROP

Sponsors and support

Primary sponsor: Artu Biologicals Europe B. V,
Lelystad, The Netherlands
Source(s) of monetary or material Support: Stichting Astmabestrijding

Intervention

Outcome measures

Primary outcome

The primary endpoint is the mean daily total symptom score as administered by the patient in the second year of treatment during the period May-August on the days at which grass-pollen counts exceeded a predefined cut-off level.
This second year can be replaced by the first year outcomes depending on the resulting pollen counts (see below).

- Cut-off level grasspollen count.

For each day during the period May-August the grass-pollen count will be determined using data from the station in Leiden. The median value of these pollen counts will be used as cut-off-level in this analysis.
Subsequently for each study day it will be determined whether the actual pollen count was above or below the resulting cut-off-level.

- Year of evaluation.

In case during the second year, in the period of May 15 until June 30, the mean daily seasonal grasspollen count is less than or equal to 25 pollen grains /m3, while this limit was exceeded for the first year, the first year diary outcomes will be considered as primary and will replace the second year diary outcomes.

The replacement for individual patients of the second year by the first year diary outcomes will also take place in case the diary during the second year is insufficiently completed (less than 50% of relevant days) while at the same time the first year is not a lost season.

- Efficacy is measured by patient-assessed symptom scores.

Main allergic symptoms are considered to be the following: sneezing; itching nose; watery running nose; nasal blockage; itching eyes.

The intensity of these symptoms is subjectively assessed according to a grading scale:
0 = no complaints;
1 = minor complaints;
2 = moderate complaints;
3 = serious complaints;
i. e. the maximal score amounts to a value of 15.

The period of measurement will be May till August in the years 2002 and 2003; 2003 and 2004. During these periods symptom scores are assessed daily by the patient and recorded in the patient diary.

Secondary outcome

1. Investigator assessed symptom-scores during the planned visits in the flowering season;

2. Number of medication free days;

3. Rescue medication;

4. Generic quality of life assessment with COOP/WONCA charts;

5. Rhinitis specific quality of life assessment (Juniper);

6. Lower airway symptoms;

7. Adverse-effects;

8. Compliance.

Study description

Background summary

Background:

Grass pollen induced rhinoconjunctivitis is common in children. Hayfever interferes with daily activities of these children and their wellbeing is severely affected.

Treatment of allergic rhinoconjunctivitis in children is symptomatic. Immunotherapy is seldom indicated in children because of possible severe, adverse events and a parental way of administration. Sublingual immunotherapy (SLIT) offers an alternative.

Study design:

Children aged 6 to 18 years known in general practice with a documented clinical history of grass pollen allergy with moderate disease intensity and a positive grass pollen specific IgE Rast test, were included in a triple blinded placebo controlled, randomised trial.

- Inclusion criteria were a total symptom score ¡Ý 5; a positive grass pollen specific IgE Rast test ¡Ý 2+; and informed consent.
- Main exclusion criteria were; inhalant therapy with daily steroids during ¡Ý 3 months a year and allergic sensitivity to epithelial in case the domestic animal is present in the family home.

Outcome measures:

Efficacy is measured by patient-assessed symptom scores. The intensity of 5 allergic symptoms: sneezing; itching nose; watery running nose; nasal blockage; itching eyes. was subjectively assessed according to a grading scale: 0 = no complaints; 1 = minor complaints; 2 = moderate complaints; 3 = serious complaints; i. e. the maximal score amounts to a value of 15.
- The periods of measurement were May till August in the years 2002 and 2003; 2003 and 2004. During these periods symptom scores were assessed daily by the patient and recorded in a patient diary.
- Main Secondary outcome measures were number of medication free days, rescue medication used, rhinitis specific quality of life, adverse effects and compliance.

Aim of the study:

To evaluate the efficacy of SLIT in comparison with placebo, on the symptoms of allergic

rhinoconjunctivitis in 6 to 18 years old children known to their GP with a rhinoconjunctivitis due to grass pollen allergy.

Study objective

In comparison with placebo SLIT will lead to a clinical relevant symptom reduction in 6 to 18 years old children with a rhinoconjunctivitis due to grass pollen allergy.

Study design

N/A

Intervention

Active treatment:

Oralgen ® Grass Pollen (9.500 BU/ml), consists of a mixture of aqueous extracts of the pollen of five grass pollen species in a glycerinated isotonic phosphate buffered solution.

The following grass pollen species are included:

¡¤Phleum pratense: Timothy, (Timotheegras)

¡¤Dactylis glomerate: Orchard grass, (Kropaar)

¡¤Anthoxantum odoratum: Vernal grass, Sweet grass, (Reukgras)

¡¤Holcus lanatus: Velvet grass, (Echte witbol)

¡¤Lolium perenne: Ryegrass, Perennial grass, (Engels raaigras)

Other ingredients include sodium chloride, sodium dihydrogen phosphate, disodium hydrogen phosphate, glycerol and water.

Control treatment:

The placebo consists of the non-active excipients, as mentioned above. Placebo treatment group.

The placebo consists of the non?active excipients, as mentioned above. Placebo treatment will be delivered in such a way that neither patients nor investigators or other research personnel can make a distinction between verum and placebo vials.

Dose schedule:

The treatment is divided in two phases: a dose escalation phase of 20 days, and a maintenance phase of 2 years. Treatment starts on day 1 with a single drop (one drop 0,05 ml = 475 BU); the dose is increased with one drop per day until day 20 (20 drops = l ml = 9.500 BU). The maintenance dose is 20 drops (=9500 BU) twice weekly.

Contacts

Public
Erasmus Medical Center, Department of General Practice,
P.O. Box 1738
Esther Röder
Molenwaterplein 40
Rotterdam 3000 DR
The Netherlands
+31 (0)10 4088014
Scientific
Erasmus Medical Center, Department of General Practice,
P.O. Box 1738
Esther Röder
Molenwaterplein 40
Rotterdam 3000 DR
The Netherlands
+31 (0)10 4088014

Eligibility criteria

Inclusion criteria

1. Age; between 6 and 18 years;

2. Patients known in general practice with documented clinical history of grass pollen allergy with moderate disease intensity as retrospectively derived from the use of symptomatic allergy medication during the previous grass pollen season, i.e. regular use of cromoglycates as nasal spray and/or eye drops, and/or regular use of anti-histamine tablets or sprays and/or limited use of local acting or systemically administered corticosteroids;

3. Moderate grass pollen allergy as retrospectively derived from allergy symptom scores during the previous grass pollen season.
Therefore, the following 5 symptoms are evaluated for the previous season:

a. Nasal blockage;

b. Sneezing;

c. Itching nose;

d. Watery running nose;

e. Itching eyes;

The intention of each of these 5 symptoms is (subjectively) assessed by the patient according to a grading scale:
0 = no complaints;
1 = minor complaints;
2 = moderate complaints;
3 = serious complaints (maximal total value is 15).
At conclusion the retrospective total value should amount at least a value of 5;

4. Positive grass pollen specific IgE Rast test, i.e. RAST score = 2+.

Exclusion criteria

1. Clinical history of severe asthmatic symptoms requiring inhalant therapy with daily pulmonary steroids during at least 3 months a year;

2. Allergic sensitivity to epithelial, in case the domestic animal is present in the family home;

3. The intention to subject the patient to surgery of the nasal cavity in the course of the study;

4. Previous immunotherapy;

5. Contraindications to sublingual immunotherapy, i.e.:

a. Malignancies and serious disorders of the oral cavity;

b. History of status asthmaticus and anaphylactic shock;

c. Aggressively developing asthmatic symptoms;

d. Serious chronic inflammations, chronic disorders associated with fever, particularly of the bronchial tubes;

e. Irreversible, secondary changes in reactive organs (emphysema, bronchiectasis);

f. Auto?immune diseases and immunodeficiency;

g. Concurrent therapy involving immunosuppressives;

h. Systemic and collagen diseases;

i. Tuberculosis of the lung and tuberculosis;

j. Serious psychological disorders;

k. Documented hypersensitivity to glycerol;

l. Pregnancy;

m. Use of ß-blockers;

6. Inability to communicate in the Dutch language;

7. Exposure to any investigational drug within 30 days of enrolment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2001
Enrollment:	204
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
Application type:	First submission

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
NTR-new	NL246
NTR-old	NTR284
Other	: N/A
ISRCTN	ISRCTN89345534

Study results

Summary results
J Allergy Clin Immunol. 2007 Apr;119(4):892-8. Epub 2007 Feb 23.