Onderzoek naar de kosten en werkzaamheid van injectiekuren (immunotherapie) bij patiënten met een allergie voor boompollen, graspollen en/of huisstofmijt.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25681

Source
Nationaal Trial Register

Brief title
AIRFORCE

Health condition

EN:
allergic rhinitis
immunotherapy
adult
costs and cost analyses

NL:
allergische rhinitis
immunotherapie
volwassenen
kosten-effectiviteit

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Cost-effectiveness: The costs per successfully treated patient, where success is based on a global assessment of efficacy by the patient after the allergen peak period in year 2 for the group that starts in 2009 and year one for the group that starts in 2010. The global assessment of efficacy is based on a rating of general improvement on a 6-point ordinal scale (much worse, a little worse, no change, a little better, much better, completely recovered). The response options “much better” and “completely recovered” define treatment success. In case of multiple allergens treatment success is defined as follows: the response option “much better” or “completely recovered” for at least one allergen and for the remaining allergens “no change”, “better”, “much better” or “completely recovered;

2. Clinical effectiveness:

A. The mean daily total rhinitis symptom score in the first year for multi-sensitized patients;

B. Daily symptom scores will be recorded during the peak exposure periods: tree pollen April 1 - May 15; grass pollen May 15 - June 30; house dust mite September 1 - October 30. (If the patient is treated with two or three allergens, symptom scores will be recorded during two or three periods) For tree and grass pollen: only days with sufficient exposure will be analyzed;

C. The intensity of 4 rhinitis symptoms (nasal blockage, watery runny nose, sneezing, itching nose) will be subjectively assessed by the patient on a scale grading from 0 = no complaints to 3 = serious complaints.

Secondary outcome

1. Cost-effectiveness:

A. The costs per unit of difference between groups in the mini Rhinitis Quality of Life Questionnaire score (mini-RQLQ-score; disease specific quality of life) during the allergen peak period in year one and two;

B. The costs per symptom-free day during the first and the second year;

C. The cost per QALY, using the EQ-5D and SF-36v2 questionnaire to derive utilities.

2. Clinical effectiveness:

A. Symptom scores after two years and in several subgroups;

B. Percentage of days with rescue medication use;

C. Percentage of ‘well days’;

D. Visual analogue scale;

E. Disease specific quality of life (mini-RQLQ);

F. Generic quality of life (EQ-5D and SF-36);

G. Global assessment;

H. Safety;

I. Adherence;

J. IgG and IgG4.

Study description

Background summary

N/A

Study objective

1. Cost-effectiveness: Subcutaneous immunotherapy (SCIT) with tree pollen (TP), grass pollen (GP), house dust mites (HDM) or combinations is cost-effective compared to usual care (UC) only.

2. Clinical effectiveness: SCIT with more than one allergen is clinically more effective - with respect to symptom improvement, medication reduction and health related quality of life - than usual care.

Study design

N/A

Intervention

Subcutaneous immunotherapy with tree pollen and/or grass pollen and/or house dust mite extract (Alutard SQ 197/293/503; ALK-Abello) + usual care vs usual care only.

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Eligibility criteria

Inclusion criteria

1. 18-45 years;

2. Clinically relevant moderate to severe allergic rhinitis due to a sensitization for one, two or three of the following
allergens: tree pollen (TP), grass pollen (GP) and/or house dust mite (HDM). For each allergen (TP, GP, HDM) the following 3 criteria are evaluated. A sensitization for an allergen is considered clinically relevant and the rhinitis moderate-severe if:

A. Specific IgE >= 0.7 kU/l (Phadia);

B. Retrospective total symptom score >=4: participants will score 4 nose symptoms (sneezing, itching nose, watery running nose, nasal blockage) during the previous peak exposure period (TP April 1-May 15; GP May 15- June 30; HDM September 1-October 31) on a

0-3 scale (0=none, 1=mild, 2=moderate, 3=severe; maximum total score=12);

C. The presence of >=1 of the following complaints due to rhinitis during the previous season: sleep disturbance; impairment of daily activities; leisure and/or sport; impairment of school or work; troublesome symptoms.

3. Signed informed consent.

Exclusion criteria

1. Severe/instable asthma:

A. FEV1 <70% predicted and/or FEV1/FVC <70;

B. Asthma exacerbation requiring prednisolon treatment, visit to a first aid station and/or hospitalisation in the preceding 12 months.

2. Specific IgE >= 0.7 kU/l to animals the patient is in daily contact with;

3. Immunotherapy in preceding 5 years;

4. Anatomical disorders of the nose;

5. Language barrier;

6. No daily access to internet (because of web based questionnaires);

7. Contraindications to immunotherapy (according to international guidelines).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2009
Enrollment:	240
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37299
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2567
NTR-old	NTR2692
CCMO	NL25370.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37299

Study results

Summary results
N/A