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

Gepubliceerd: 13-01-2011 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25681

Bron
Nationaal Trial Register

Verkorte titel
AIRFORCE

Aandoening

EN:
allergic rhinitis
immunotherapy
adult
costs and cost analyses

NL:
allergische rhinitis
immunotherapie
volwassenen
kosten-effectiviteit

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37299
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A