Cost-effectiveness of subcutaneous immunotherapy in adults with allergic rhinitis

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

Summary

ID

NL-OMON37299

Source
ToetsingOnline

Brief title
AIRFORCE

Condition

- Allergic conditions

Synonym
allergic rhinitis, hay fever

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: adult, allergic rhinitis, costs and cost analyses, immunotherapy

Outcome measures

Primary outcome

Cost-effectiveness: the costs per successfully treated patient, based on a global assessment of efficacy by the patient after the allergen peak exposure period in year 2 for the group that starts in 2009 and year one for the group that starts in 2010.

Clinical effectiveness: the difference in mean daily total nasal symptom scores for multi-sensitized patients in the peak exposure periods after one year.

Secondary outcome

Cost-effectiveness: the costs per symptom-free day, the costs per QALY, the costs per unit of difference between groups in the RQLQ score (disease specific quality of life).

Clinical effectiveness: the difference in mean daily total symptom scores after two years and in several subgroups; percentage of days with anti-allergic medication use, the percentage of *well days*, visual analogue scale; disease specific quality of life; global assessment; safety and adherence.

Study description

Background summary

The prevalence of allergic rhinitis is estimated at 23%. Reported annual costs of allergic rhinitis in different countries vary from ¤ 1,543 to ¤ 4,260 per adult. Apart from usual care (UC), which consists of symptomatic, anti-allergic medication, subcutaneous immunotherapy (SCIT) with allergens has proven

long-term effects on symptoms of both rhinitis and asthma. However SCIT is expensive and its cost-effectiveness has not been proven. Furthermore, no data are available on the efficacy of SCIT in multi-sensitized patients using more than one allergen.

Study objective

First, to estimate the cost-effectiveness of SCIT with tree pollen (TP), grass pollen (GP), and house dust mites (HDM) - the most prevalent allergies treated with SCIT - or combinations compared with UC. Second, to estimate the clinical efficacy of SCIT with a combination of two or three allergens (TP/GP/HDM) in multi-sensitized patients.

Study design

Multicenter randomized controlled open clinical trial with two parallel treatment groups

Intervention

SCIT with TP, GP, HDM or a combination plus UC or UC only, for 2 years (start autumn 2009) or 1 year (start autumn 2010).

Study burden and risks

Screening - 1 contact by phone and 1 site visit (45-60 min): questionnaire, one blood sample, physical examination (length/weight, if applicable nose inspection) and if applicable one lung function test (spirometry).
During the study - No extra site visits. Participants will be contacted by phone every 3 months (10 minutes per call). One blood sample after one year. Diary card in peak exposure period: 6-8 weeks per allergen (5-10 minutes per day). Questionnaires outside peak exposure period: approximately every 2 months (15-20 minutes per assessment).
Immunotherapy - The allergen extracts for subcutaneous administration are registered. Local side effects (itching, redness, swelling) are frequent and usually mild. Systemic allergic reactions are rare.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* 18-45 years
* 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:
1) specific IgE >=0.7 kU/l (Phadia)
2) retrospective total symptom score (RSS) >=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).
3) 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 (QOLs).
Protocol exception: A sensitization for an allergen (specific IgE >=0.7 kU/l (Phadia)) is also considered clinically relevant and the rhinitis moderate-severe if: RSS=3 and QOLs >=3 or QOLs=0 and RSS >=9.
* Signed informed consent

Exclusion criteria

* Severe/instable asthma:
- FEV1 <=70% predicted and/or FEV1/FVC <70
- Asthma exacerbation requiring prednisolon treatment, visit to a first aid station and/or hospitalisation in the preceding 12 months.
* Specific IgE >= 0.7 kU/l to animals the patient is in daily contact with
* Immunotherapy in preceding 5 years
* Anatomical disorders of the nose
* Language barrier
* No daily access to internet (because of web based questionnaires)
* Contraindications to immunotherapy (according to international guidelines; i.e. history of anaphylaxis; immunosuppressive treatment etc)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2009
Enrollment:	240
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Alutard SQ 293 Grassen-5 (RVG 16445)
Generic name:	Engels raaigras, Beemdlangbloem, Kropaar, Grote vossestaart
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Alutard SQ 503 (RVG 16469)
Generic name:	Huisstofmijten (Dermatophagoides pteronyssinus)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-08-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-05-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25681
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-011827-30-NL
CCMO	NL25370.078.09
OMON	NL-OMON25681