

Immunotherapy
How/who to refer
Investigations required
How it is done/practical issues
Costs, benefits

Dr Tak Chin (Consultant Allergist)
Southampton General Hospital

Immunotherapy is
the “treatment of disease by
inducing, enhancing, or suppressing
an immune response”

Immunomodulators

Activation immunotherapies

- Cancer immunotherapy

- Immune recovery

- Vaccination

- Aging immunotherapy

Suppression immunotherapies

- Immunosuppressive drugs

- Immune tolerance

- Allergen immunotherapy

- Helminthic therapies

Terminology

Allergen immunotherapy (AIT)

Allergen-specific immunotherapy (ASIT)

Specific immunotherapy (SIT)

Immunotherapy (IT)

Hyposensitisation/hyposensitization

Desensitisation/desensitization

Allergy vaccination

Active immunisation/immunization

Anti-anaphylaxis

Prophylactic inoculation

NEWS AND COMMENTARIES

Allergen immunotherapy: a new semantic framework from the European Academy of Allergy and Clinical Immunology/American Academy of Allergy, Asthma and Immunology/PRACTALL Consensus Report

DOI:10.1111/all.12180

Immunotherapy for allergic diseases has entered a new age, marked by the development of a small number of new therapeutic classes of standardized allergen formulations registered as pharmaceutical specialties after large, robust, pivotal Phase III clinical trials (1). Furthermore, concepts in general medicine and our understanding of the immune system's functions have changed substantially. These developments in pathophysiology, pharmacology, and clinical practice suggest that there is a need to change and align our current semantic frameworks about the terminology used for immunotherapy

mobilizing or manipulating a patient's immune system to treat or cure disease, and (iv) a general term encompassing active and passive immunization. Immunotherapy can be prophylactic or therapeutic. It may involve the administration of antibodies, antibody fragments, peptides of antigens, polypeptide allergens, immunosuppressants, immunomodulators, nucleic acids, small molecules, and even immune system cells and can be used to treat cancer, heart failure, organ transplantation, autoimmune disease, and, of course, a number of allergic conditions.

Assuming that the term 'immunotherapy' is relevant but

Definition

Allergen immunotherapy

is the administration of slowly increasing doses of specifically relevant allergen in the treatment of IgE-mediated allergic diseases until a maintenance dosage is achieved or the patient is free of symptoms.

Mithridates VI

King of Kings^[1]



Mithridates VI from the Musée du Louvre

Reign	120–63 BC
Successor	Pharnaces II of Pontus
Father	Mithridates V of Pontus
Mother	Laodice VI

132 – 63 BC: King Mithridates VI of Pontos – snake venom

A



B



Leonhardt Noon (1878–1911) & John Freeman (1877–1962)

bleeding, and then administer salines. In the other 14 cases so treated the condition of the patients permitted of the delay necessary for preparatory treatment and for the removal of all blood clots from the abdomen.

The crisis having passed, and when the case is first seen subsequent to the formation of a distinct and encapsulated hæmatocele, more conservative treatment is warranted. With rest in bed the majority of such cases undergo complete absorption, the only indication for operative interference being the possibility of secondary rupture of the hæmatocele demanding coeliotomy, or infection of the sac, which is best treated by vaginal incision and drainage. Against an entirely expectant line of treatment the element of time has to be considered, especially with hospital patients. Large hæmatoceles may take weeks to undergo complete absorption, which loss of time may be prevented by the safe proceeding of vaginal incision and drainage. Of my six cases so treated five were typical cases of retro-uterine hæmatoceles, and the patients left the hospital within three weeks from date of admission. In the remaining case of hæmatoma, abdominal section having shown that the blood was encapsulated in the broad ligament, the abdomen was closed and the case further treated by vaginal incision and drainage.

Dundee.

PROPHYLACTIC INOCULATION AGAINST HAY FEVER.

BY L. NOON, B.C. CANTAB., F.R.C.S. ENG.

(From the Laboratory of the Department for Therapeutic Inoculation, St. Mary's Hospital.)

HAY fever is a form of recurrent catarrh affecting certain individuals during the months of May, June, and July. It is caused by a soluble toxin found in the pollen of grasses. The patients present the idiosyncrasy of being sensitive to this toxin, which is innocuous to normal individuals. The idiosyncrasy may be detected during any season of the year by dropping a little of an extract of grass pollen into the eye of the suspected individual; a reaction, described more fully below, will be obtained in the case of a hay fever patient, but a normal man will show no effect.

Bostock (1819)¹ recognised the seasonal recurrence of hay fever as separating it from other forms of catarrh. Blackley (1873)² advanced much evidence in favour of the pollen theory of its causation, but we owe chiefly to Dunbar (1903)³ the exhaustive scientific proof of this theory. Dunbar showed that

use of this remedy, but admittedly in exceptional cases; and where the conditions are not understood and the experience is not constantly repeated, one must hesitate to attribute the result to the cause cited. On general grounds a much more satisfactory result would be expected from the induction of an active immunity, and it seemed worth while to put this expectation to the test of experiment. The questions to be answered are as to what degree of immunity can be induced in hay fever patients by inoculations of pollen toxin, how these inoculations may best be regulated, and whether the affection can by this means be permanently cured.

With this end in view the experiments here described were undertaken in the past autumn, winter, and spring to study the reaction of hay fever patients towards inoculations of pollen toxin. The off season of the year, when the patients were not exposed to spontaneous inoculations, was favourable to this investigation, as the scheme of dosage was then not liable to be upset by spontaneous absorption of toxin from the air, laden with actively poisonous pollen grains. The plan of experiment was to obtain a numerical measure of the sensitiveness of the patients to the pollen toxin and to observe whether this was increased or decreased by subcutaneous inoculations of various quantities of pollen toxin. These observations can be conveniently carried out by the method described below, and it was found that, with well-regulated dosage, it was possible in every case to raise the patient's resistance, to a marked degree, within the lapse of a few months, while, on the other hand, ill-regulated dosage was at once made evident by a decrease in the resisting power.

The pollen extract used was prepared by Dunbar's method of extraction with distilled water, aided by freezing and thawing several times. The extracts were boiled for ten minutes after having been sealed in glass tubes; this treatment was not found to decrease their activity at all. The pollens tested were grass pollens of different species—*Phleum pratense*, *Poa trivialis*, *Holcus lanatus*, and *Agropyrum caninum*. These pollens were all found capable of exciting an energetic reaction when instilled into the conjunctival sac of hay fever patients. Timothy grass (*Phleum pratense*) was found to yield the most active extract, and this extract was consequently used throughout the rest of the experiments. One gramme of pollen was extracted with 50 c.c. of water. The activity of this extract may be judged from the fact that one drop of a five thousand-fold dilution is sufficient to excite a distinct reaction in the conjunctiva of the more sensitive patients.

In order to express the strengths of pollen extracts used in testing patients and the doses of pollen toxin given sub-

William Frankland
MBE



William Frankland in 2006

Born	Alfred William Frankland 19 March 1912 (age 104) Sussex, England, UK
Nationality	British
Education	St. Bees School
Alma mater	University of Oxford

Frankland AW. High and low dosage pollen extract treatment in summer hay fever and asthma. Acta Allergol 1955; 9: 183–187.

Format: Abstract Send to [N Engl J Med.](#) 1978 Jul 27;299(4):157-61.**A controlled trial of immunotherapy in insect hypersensitivity.**[Hunt KJ](#), [Valentine MD](#), [Sobotka AK](#), [Benton AW](#), [Amodio FJ](#), [Lichtenstein LM](#).**Abstract**

Insect hypersensitivity is currently treated by immunization using whole-body extracts. We compared this regimen with immunotherapy using insect venoms or placebo in groups of 20 patients matched for history and sensitivity, as judged by venom skin test, histamine release and IgE antibody to venom. After six to 10 weeks of immunization, systemic reactions to stings occurred in seven of 12, seven of 11, and one of 18 patients treated with placebo, whole-body extract, and venom, respectively. Placebo and whole-body extract gave similar results and were significantly less effective than venom immunotherapy (P less than 0.01). The 14 patients with failure of treatment with whole-body extract and placebo were subsequently provided with venom immunotherapy; one reacted to a subsequent sting. We conclude that venom immunotherapy is clinically superior to therapy on whole-body extract or placebo.

PMID: 78446 DOI: [10.1056/NEJM197807272990401](#)

[PubMed - indexed for MEDLINE]

Adjuvants (tyrosine, calcium phosphate, MPL, CpG-oligonucleotides..)

Allergoids (formaldehyde, glutaraldehyde, aluminium hydroxide..)

Histamine

Peptone

Coca's solution

Ether

Ethanol

Aqueous

WHO Position Paper

Allergen immunotherapy: therapeutic vaccines for allergic diseases

Geneva: January 27—29 1997

American Academy of Allergy, Asthma, and Immunology (AAAAI)
European Academy of Allergy and Clinical Immunology (EAACI)
European Society of Pediatric Allergy and Clinical Immunology (ESPACI)
IUIS/IAACI Subcommittee on Allergen Standardization
Japanese Society of Allergology
National Institute of Allergy and Infectious Diseases (NIAID)
World Health Organization (WHO)

endorsed by

American College of Allergy, Asthma, and Immunology (ACAAI)
International Association of Asthmology (Interasma)

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Panel members

E. Alvarez-Cuesta (Spain)
O. W. Canonica (Italy)
M. D. Chapman (USA)

Allergen Immunotherapy

How/who to refer



CSM UPDATE

Desensitising vaccines

DESENSITISATION THERAPY (hyposensitisation or immunotherapy) has been used to treat allergic disorders since the early 1900s. It aims to reduce the susceptibility of patients to symptoms induced by specific environmental allergens to which they have been found to be sensitive. The two types of desensitising vaccines most commonly used in the United Kingdom are extracts of house dust mite and grass pollen. Extracts of a large variety of other allergens, including bee and wasp venoms, are also available and are given either singly or in combination. A confusing number of different units are

TABLE II—Number of cases and incidence (per course of treatment) of serious adverse reactions to desensitising agents reported in the UK. Figures given in parentheses after each agent are number of courses sold during the stated period

	Anaphylaxis	Bronchospasm	Anaphylaxis + bronchospasm	Death
<i>Extracts of house dust mite</i>				
Norisen (24 000; 1978-86):				
No of cases	39	19	58	3
Estimated incidence	1/615	1/1263	1/413	1/8000
Migen (114 600; 1973-86):				
No of cases	19	33	52	4
Estimated incidence	1/6031	1/3472	1/2203	1/28 650

TABLE I—Details of 26 patients* who died from anaphylaxis induced by desensitising agents†

	No		No
Indication for treatment:		Adverse reactions reported to previous injections in final course of treatment:	
Asthma	16	Yes	6
Hay fever	1	No	20
Unknown	9		
Type of treatment:		Time of onset of reaction:	
Normal course	16‡	<10 minutes	14
Maintenance injections	4	<30 minutes	4
Unknown	6	<90 minutes	2
		Unknown	6

* 13 female, 12 male, one of unknown sex; mean age 31 (range 11-57) years.

† Specific Desensitising Vaccine in 16 cases, Migen in four, Norisen in three, Pollinex in two, and Alavac-S in one.

‡ Five had undergone previous courses without adverse reactions.

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No of cases	19	33	52	4
Estimated incidence	1/6031	1/3472	1/2203	1/28 650
<i>Pollen extracts</i>				
Norisen Grass (43 500; 1978-86):				
No of cases	14	14	28	0
Estimated incidence	1/3107	1/3107	1/1553	
Pollinex (643 500; 1974-86):				
No of cases	30	27	57	2
Estimated incidence	1/21 450	1/23 833	1/11 289	1/321 750
Alavac-P (39 500; 1979-86):				
No of cases	3	7	10	0
Estimated incidence	1/13 166	1/5642	1/3950	
Spectralgen Pollen (500§; 1982-6):				
No of cases	1	7	8	0
Estimated incidence	1/500	1/71	1/62.5	
<i>Extracts of many different allergens</i>				
Norisen* (67 000; 1978-86):				
No of cases	17	8	25	0
Estimated incidence	1/3941	1/8375	1/2680	
Conjuvac (1830; 1981-6):				
No of cases	1	3	4	0
Estimated incidence	1/1830	1/610	1/457	
Allpyral (389 961; 1978-86):				
No of cases	14	12	26	0
Estimated incidence	1/27 854	1/32 496	1/14 998	
Alavac-S (65 300; 1979-86):				
No of cases	11	5	16	0†
Estimated incidence	1/5936	1/13 060	1/4081	
Specific Desensitising Vaccine (67 900; 1979-86):				
No of cases	39	29	68	5‡
Estimated incidence	1/1741	1/2341	1/998	1/13 580
<i>Wasp and bee venoms</i>				
Pharmalgen (1500§; 1980-6):				
No of cases	2	3	5	0
Estimated incidence	1/750	1/500	1/300	
Albay (182):				
No of cases	0	0	0	0
Estimated incidence				

*Excluding extracts of 100% house dust mite and grass pollen. §Numbers of patients.

†One death in 1972; ‡eleven additional deaths during 1957-79 (data on number of courses of treatment sold unavailable).

Allergen Immunotherapy

How/who to refer

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Beekeeper cured of life threatening allergy after three years of 'sting' treatment

A dedicated beekeeper who almost died from a bee sting underwent three years of venom injections so he could overcome his allergy



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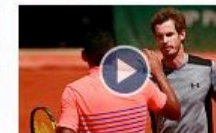
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Murray reacts to win over Kyrgios



Crowd 'lifts' bus off trapped unicyclist



Woman meets man with dead brother's face

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Venom immunotherapy for preventing allergic reactions to insect stings (Review)

Boyle RJ, Elremeli M, Hockenhull J, Cherry MG, Bulsara MK, Daniels M, Oude Elberink J

Authors' conclusions

Venom immunotherapy using extracted insect venom to be an effective therapy for preventing further allergic reactions to insect stings, which can improve quality of life. The treatment carries a small but significant risk of systemic adverse reaction.

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Bee sting vaccine on the NHS

A 'vaccine' that protects people vulnerable to severe reactions from bee and wasps stings is to be made available on the NHS.




People who have already suffered a serious reaction to a bee or wasp sting will be able to ask their GP for the 'vaccine' Photo: GETTY IMAGES



By Stephen Adams, Medical Correspondent

6:20AM BST 30 Sep 2011

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Pharmalgen for the treatment of bee and wasp venom allergy

Technology appraisal guidance [TA246] Published date: 22 February 2012

Guidance

Tools and resources

Information for the public

History


Overview

1 Guidance

2 Clinical need and practice

3 The technologies

Guidance

 NICE Pathway - Anaphylaxis

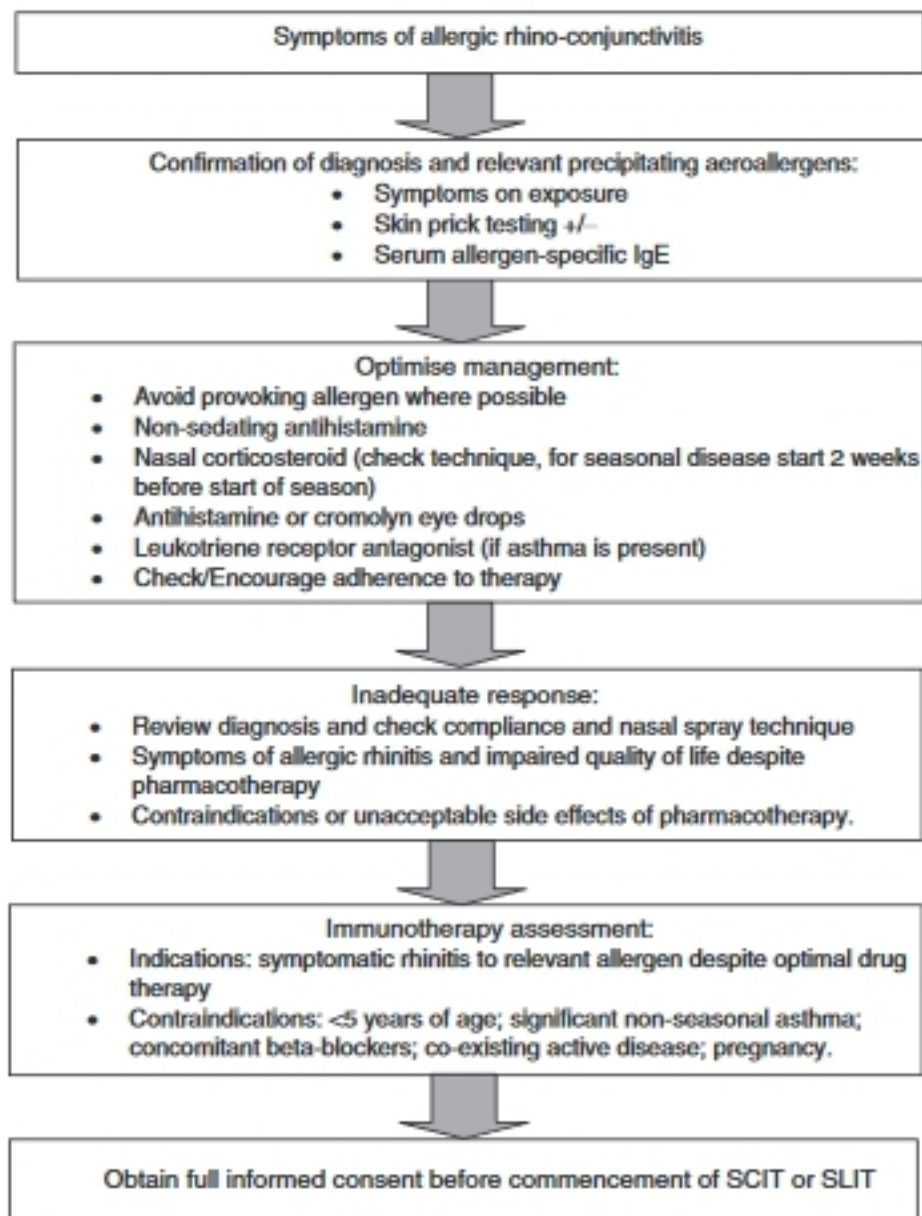
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Immunotherapy for allergic rhinitis

S. M. Walker¹, S. R. Durham², S. J. Till³, G. Roberts⁴, C. J. Corrigan⁵, S. C. Leech⁶, M. T. Krishna⁷, R. K. Rajakulasingham⁸, A. Williams⁸, J. Chantrell⁹, L. Dixon¹⁰, A. J. Frew¹¹ and S. M. Nasser¹²

¹Education for Health, The Athenaeum, Warwick, UK, ²Royal Brompton and Harefield Hospitals, NHS Trust and Imperial College, London, UK, ³Department of Asthma, Allergy and Respiratory Science, Division of Asthma, Allergy & Lung Biology, MRC and Asthma UK Centre for Allergic Mechanisms of Asthma, Kings College London, UK, ⁴Department of Child Health, University of Southampton School of Medicine, Southampton, UK, ⁵Division of Asthma, Allergy and Lung Biology, King's College London, Medical Research Council, and Asthma UK Centre in Allergic Mechanisms of Asthma, London, UK, ⁶Department of Child Health, King's College Hospital, London, UK, ⁷Birmingham Heartlands Hospital, Birmingham UK, ⁸Homerton University Hospital, NHS Foundation Trust, London, UK, ⁹University Hospitals of Leicester, Glenfield Hospital Site, Leicester, UK, ¹⁰Royal Victoria Infirmary, Newcastle Upon Tyne, UK, ¹¹Brighton & Sussex University Hospitals NHS Trust, Royal Sussex County Hospital, Brighton, UK and ¹²Cambridge University Hospital, NHS Foundation Trust, Cambridge, UK

Who should undergo immunotherapy? When should treatment be started?



SCIT for Allergic Rhinitis



Allergen injection immunotherapy for seasonal allergic rhinitis (Review)

Calderon MA, Alves B, Jacobson M, Hurwitz B, Sheikh A, Durham S

April 2008

1111 publications - 51 satisfied inclusion criteria. 2871 participants (1645 active, 1226 placebo). Average 18 injections. Duration of immunotherapy 3 days - 3 years. Symptom score data from 15 trials were suitable for meta-analysis - overall reduction in the immunotherapy group (SMD -0.73 (95% CI -0.97 to -0.50, $P < 0.00001$)). Medication score data from 13 trials - overall reduction in the immunotherapy group (SMD of -0.57 (95% CI -0.82 to -0.33, $p < 0.00001$)). Adrenaline was given in 0.13% (19 of 14085 injections). There were no fatalities.

SLIT for Allergic Rhinitis



Sublingual immunotherapy for allergic rhinitis (Review)

Radulovic S, Calderon MA, Wilson D, Durham S

December 2010

60 randomised controlled trials - 49 suitable for pooling in meta-analyses (2333 SLIT, 2256 placebo participants).

Overall significant reduction in symptoms (SMD -0.49; 95% confidence interval (CI) -0.64 to -0.34, $P < 0.00001$) and medication requirements (SMD -0.32; 95% CI -0.43 to -0.21, $P < 0.00001$) in participants receiving sublingual immunotherapy compared to placebo.

None of the trials reported severe systemic reactions or anaphylaxis.

None of the systemic reactions reported required the use of adrenaline.

Allergen Immunotherapy

Investigations required

- Confirmation of diagnosis and relevant precipitating allergen
- Can be complex.. full list of investigations in BSACI & EAACI Guidelines for Insect Venom Anaphylaxis and Allergic Rhinitis

Allergen Immunotherapy

How it is done/practical issues

AIT Modalities

- Allergen extract/formulation/preparation
- Aqueous vs Depot/Semi-depot
- Allergens vs Allergoids
- Adjuvant
- Route (subcutaneous (SCIT), sublingual (SLIT)..)
- Start time (continuous, co-seasonal, pre-seasonal..)
- Duration
- Up-dosing and maintenance
 - conventional
 - cluster-rush
 - rush
 - ultra-rush



03:03 / 27:47



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The following equipment is required:

- Adrenaline (1 : 1000) should be drawn up or immediately available.
- Antihistamines and corticosteroids (intravenous and oral preparations).
- β -agonist (with facilities for inhalation with or without a spacer and nebulization),
- Saline/colloids for intravenous infusion.
- Oxygen and suction equipment should be immediately available.
- Equipment for monitoring blood pressure and oxygen saturation.
- Nebulizer and masks.
- Peak flow meter and mouthpieces.
- Syringes, needles and intravenous cannulae.

Box 2. Factors associated with severe adverse reactions during subcutaneous immunotherapy are as follows

Co-existing asthma

Poorly controlled asthma

History of previous systemic reaction(s) to immunotherapy

Delay or omission of the use of adrenaline in treating anaphylaxis

Inappropriate selection of candidates for injection immunotherapy

Dosing errors

Changeover between batches of allergen; reaction to the first dose of a new vial

Lack of cardio-respiratory resuscitation facilities

Commencing an updosing immunotherapy regimen during the pollen season

Allergen Immunotherapy

Costs, benefits

**LIVERPOOL REVIEWS AND
IMPLEMENTATION GROUP (LRiG)**

**The clinical and cost effectiveness
of Pharmedgen® for the treatment
of bee and wasp venom allergy**

SCIT for Allergic Rhinitis



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SLIT for Allergic Rhinitis



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December 2010

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SCIT for Asthma



Injection allergen immunotherapy for asthma (Review)

Abramson MJ, Puy RM, Weiner JM

August 2010

*88 trials were included - 42 house dust mite; 27 pollen; 10 animal dander; 2 Cladosporium mould; 2 latex; 6 multiple allergens.
Concealment of allocation was assessed as clearly adequate in only 16 of these trials.
Significant heterogeneity.
Overall, significant reduction in asthma symptoms and medication, and improvement in bronchial hyper-reactivity following immunotherapy.*

SCIT for Asthma



Injection allergen immunotherapy for asthma (Review)

Abramson MJ, Puy RM, Weiner JM

August 2010

Significant improvement in asthma symptom scores (standardised mean difference -0.59, 95% confidence interval -0.83 to -0.35)

Number needed to treat to avoid deterioration in asthma symptoms = 3 (95% CI 3 to 5).

Number needed to treat to avoid requiring increased medication = 4 (95% CI 3 to 6).

Allergen immunotherapy significantly reduced allergen specific bronchial hyper-reactivity, with some reduction in non-specific bronchial hyper-reactivity as well.

Number needed to harm = 16 (local adverse reaction); 9 (systemic reaction).

SLIT for Asthma



Sublingual immunotherapy for asthma (Review)

Normansell R, Kew KM, Bridgman AL

August 2015

Lack of data for important outcomes such as exacerbations and quality of life and use of different unvalidated symptom and medication scores have limited our ability to draw a clinically useful conclusion. Further research using validated scales and important outcomes for patients and decision makers is needed so that SLIT can be properly assessed as clinical treatment for asthma.

Very few serious adverse events, but most studies have included patients with intermittent or mild asthma, so we cannot comment on the safety of SLIT for those with moderate or severe asthma. SLIT is associated with increased risk of all adverse events.

Allergy. 2006 Jul;61(7):855-9.

Five-year follow-up on the PAT study: specific immunotherapy and long-term prevention of asthma in children.

Niggemann B¹, Jacobsen L, Dreborg S, Ferdousi HA, Halken S, Høst A, Koivikko A, Koller D, Norberg LA, Urbanek R, Valovirta E, Wahn U, Möller C; PAT Investigator Group.

⊕ Author information

Abstract

BACKGROUND: A 3-year course of specific immunotherapy (SIT) in children with hay fever to grass and/or birch pollen significantly reduced the risk of developing asthma. To investigate the long-term preventive effect, we performed a follow up--2 years after termination of immunotherapy.

METHODS: A total of 183 children, aged 6-14 years with grass and/or birch pollen allergy could be investigated 2 years after discontinuation of SIT or no treatment. Conjunctival provocation tests (CPTs) and methacholine bronchial provocation tests were carried out during the season and winter after 5 years. The development of asthma was assessed by clinical evaluation.

RESULTS: The significant improvement in hay fever and CPT results observed after 3 years of SIT persisted at the 5-year follow-up. No difference in bronchial responsiveness to methacholine was found after 5 years because of spontaneous improvement during the follow-up period in the control patients. The immunotherapy-treated children had significantly less asthma after 5 years as evaluated by clinical symptoms [odds ratio 2.68 (1.3-5.7)] in favor of SIT for prevention of development of asthma and significantly less patients reported an increase in asthma scores ($P < 0.01$).

CONCLUSION: Immunotherapy for 3 years with standardized allergen extracts of grass and/or birch shows long-term clinical effect and preventive effect on development of asthma in children with seasonal rhinoconjunctivitis.

Allergy immunotherapy for allergic rhinitis effectively prevents asthma: Results from a large retrospective cohort study

[Jochen Schmitt](#), MD, MPH  , [Kristin Schwarz](#), [Erich Stadler](#), [Eike Gunther Wüstenberg](#), MD

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Methods

Using routine health care data from German National Health Insurance beneficiaries, we identified a consecutive cohort of 118,754 patients with AR but without asthma who had not received AIT in 2005. These patients were stratified into one group starting AIT in 2006 and one group receiving no AIT in 2006. Both groups were observed regarding the risk of incident asthma in 2007 to 2012. Risk ratios (RRs) were calculated with generalized linear models by using a Poisson link function with robust error variance and adjustment for age, sex, health care use because of AR, and use of antihistamines.

Results

In a total of 2431 (2.0%) patients, AIT was started in 2006. Asthma was newly diagnosed from 2007-2012 in 1646 (1.4%) patients. The risk of incident asthma was significantly lower in patients exposed to AIT (RR, 0.60; 95% CI, 0.42-0.84) compared with patients receiving no AIT in 2006. Sensitivity analyses suggested significant preventive effects of subcutaneous immunotherapy (RR, 0.54; 95% CI, 0.38-0.84) and AIT including native (nonallergoid) allergens (RR, 0.22; 95% CI, 0.02-0.68). AIT for 3 or more years tended to have stronger preventive effects than AIT for less than 3 years.

Conclusion

AIT effectively prevents asthma in patients with AR in a real-world setting. Confounding by indication cannot be excluded but would lead to an underestimation of the true preventive effects of AIT.

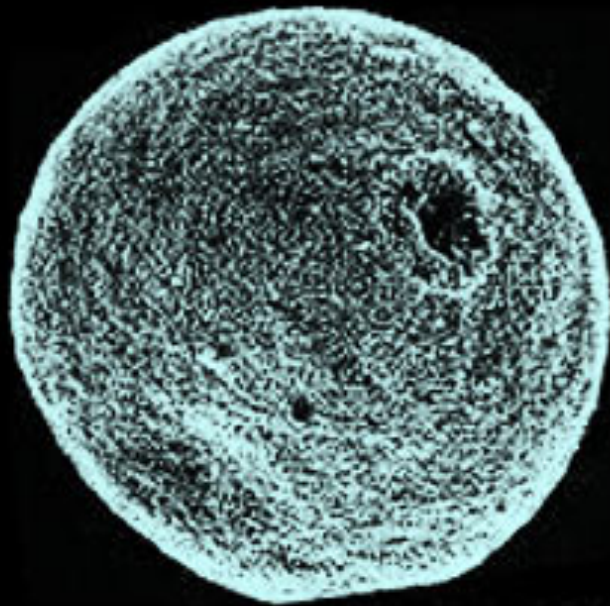
DAILY NEWS 30 January 2014

Peanut allergy cured in children using immunotherapy

By Andy Coghlan



POLLEN



DEATH STAR



ANY QUESTIONS?