

Tapering off Inhaled Corticosteroids in Asthma patients after Reducation of Allergens.

No registrations found.

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

Summary

ID

NL-OMON23474

Source

Nationaal Trial Register

Brief title

TICARA

Health condition

(Allergic) asthma.

Sponsors and support

Primary sponsor: Research Institute Caphri / Maastricht University.

Source(s) of monetary or material Support: ZonNW (NWO) 904-58-111

Nederlands Astmafonds 98.55

Astra Zeneca

Boehringer Ingelheim

Intervention

Outcome measures

Primary outcome

Use of inhaled corticosteroids.

Secondary outcome

1. Asthma control;
2. Symptoms (dyspnoea, wheezing, coughing);
3. Peak flow parameters (morning peak flow, peak flow variability).

Study description

Background summary

In this study the hypothesis was tested whether allergen avoidance allows tapering off inhaled corticosteroids (ICS) in house dust mite allergic asthma patients.

Asthma patients between 16 and 60 years using ICS were selected from general practices and the general population. With a RAST allergy for house dust mite and other common allergens was determined.

Patients having an allergy to cats and dogs whilst these animals were present in the house were excluded. Patients were instructed by the GP or a nurse to use a self-management plan to adjust the dose of ICS.

After a baseline period of three months patients received house dust mite impermeable bed covers or placebo covers. Follow-up period was two years. Medication use, symptoms and peakflow were recorded in diaries. Exposure to house dust mite allergens was determined by means of dust samples taken from mattresses, by vacuum cleaning in a standardised way.

Study objective

Allergen avoidance allows tapering off inhaled corticosteroids (ICS) in house dust mite allergic asthma patients.

Study design

N/A

Intervention

All patients have been trained to use a self-management plan to adjust the dose of inhaled corticosteroids to symptoms and peak expiratory flow value.

After a run-in period of 3 months the intervention period with placebo controlled allergen avoidance started.

The participants in the intervention group received house dust mite impermeable covers for

mattress, pillow and bedding.

The control group received placebo, house dust mite permeable, covers.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age of 16-60 year;
2. Treatment for asthma by the GP;
3. Use of inhaled corticosteroids;
4. Allergy for house dust mite allergens.

Exclusion criteria

1. Serious diseases other than asthma with;
2. A low survival rate;
3. Other diseases, which influence bronchial symptoms and/ or lung function;

4. Exacerbation within one month before the start of the study;
5. The use of oral steroids or inhaled cromoglycates;
6. Use of house dust mite impermeable mattress/bedding covers;
7. Allergy to cats or dogs while keeping these pets.

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):	01-01-1999
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion	
Date:	12-09-2005
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	NL332
NTR-old	NTR370
Other	: N/A
ISRCTN	ISRCTN32862552

Study results

Summary results

1. de Vries MP, van Schayck CP Bestaat er een verband tussen het optreden van luchtweginfecties op jonge leeftijd en het ontstaan van atopie? Longartsenvademecum, nummer 2- februari 2000;

2. van den Bemt L, van Knapen L, de Vries MP, Jansen M, Cloosterman S, van Schayck CP. Clinical effectiveness of a mite-allergen impermeable bed covering system in asthmatic mite-sensitive patients. J Allergy Clin Immun, 2004, 114 (4): 858-62;

3. de Vries MP, van den Bemt L, van der Mooren FM, Muris JWM, van Schayck CP. The prevalence of house dust mite allergy and the use of HDM impermeable covers in a primary care population of patients with persistent asthma in the Netherlands. Prim Care Respir J, 2005, 14 (4): 210-4;

4. de Vries MP, van den Bemt L, Lince S, Muris JWM, Thoonen BPA, van Schayck CP. Factors associated with asthma control. J Asthma, 2005, in press.