

# The effect of mite allergen avoidance by the use of allergen impermeable bedding, on asthma control in adults

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/12/2008	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Ashley Woodcock

### Contact details

Lung Function Unit  
North West Lung Centre  
Wythenshawe Hospital  
Southmoor Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9LT

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

### Acronym

SMAC

### Study objectives

Asthma is an increasing clinical problem and allergy to indoor allergens is an important cause. The hypothesis that house dust mite allergen avoidance, by the use of allergen impermeable bedding, improves asthma control will be tested. The trial will assess over one year both the ability of this approach to improve lung function and quality of life whilst reducing symptoms and prn-beta-agonist use and, in the second six month period, the potential for a reduction in regular prophylactic maintenance therapy.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied

Respiratory tract diseases: Asthma

### Interventions

Asthmatic patients are randomly allocated to receive either active allergen-proof covers for mattress, duvet and pillows, or a set of dummy covers which look and feel similar to the allergen-proof covers but do not form a protective barrier. Covers remain on their beds for one year.

### Intervention Type

Other

## **Phase**

Not Specified

## **Primary outcome measure**

1. Average morning peak expiratory flow rate in the four week period prior to the six month visit
2. Complete withdrawal from steroids in second six months

## **Secondary outcome measures**

1. Use of beta agonist rescue medication and median symptom score in the four week period prior to the six month visit
2. Number of exacerbations in the six month period
3. Quality of life (St George's Respiratory Questionnaire and Short Form 36) at six month and twelve months
4. Cost of treatment and time off work (Health Care Questionnaire)
5. Change in dose of inhaled steroid in second six months

## **Overall study start date**

01/05/1998

## **Completion date**

01/04/2001

# **Eligibility**

## **Key inclusion criteria**

1800 asthmatics ages 18-50 years at recruitment

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Upper age limit**

50 Years

## **Sex**

Not Specified

## **Target number of participants**

1800

## **Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/05/1998

**Date of final enrolment**

01/04/2001

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Lung Function Unit**

Manchester

United Kingdom

M23 9LT

## **Sponsor information**

**Organisation**

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

NHS Asthma National Research and Development Programme (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	17/07/2003		Yes	No