

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

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

Completion date

01/04/2001

Eligibility

Key inclusion criteria

1800 asthmatics ages 18-50 years at recruitment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

Not Specified

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

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Asthma National Research and Development Programme (UK)

Results and Publications

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?
Results article	results	17/07/2003		Yes	No