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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 09/12/2008	**Condition category** Respiratory	

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?
Results article	results	17/07/2003		Yes	No