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Preventing asthma exacerbations by avoiding mite allergen

Submission date 25/07/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/07/2012	**Overall study status** Completed	
Last Edited 13/03/2017	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11078

Study information

Scientific Title
Preventing asthma exacerbations in children by avoiding mite allergen

Study objectives
Asthma is a common disease in children and for most symptoms are well controlled with regular inhaler medications. However, many will still experience exacerbations (times when their symptoms become out of control) and these will result in school absenteeism, visits to the GP or A&E and even hospital admission. Previous studies have identified risk factors for exacerbations and these include viral infections and exposure to allergens that the child is sensitised to. In fact these two factors together are the biggest risk factor of all. The commonest allergen asthmatic children are sensitised and exposed to in the UK is house dust mite (HDM) allergen. These mites live in beds and bedding, carpets, curtains, soft toys and clothes. Close contact is most frequent at night from our bedding. Exposure to these allergens can be reduced by installing miteproof bedding covers (mattress, pillow and duvet).The purpose of the study is to find out whether reducing exposure to HDM allergen by using miteimpermeable bedding covers will reduce the number of exacerbations an asthmatic child has over the following 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11/ NW/0262

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Asthma in paediatrics

Interventions
The bedding covers will be tested by comparing them to placebo (dummy) covers. To do this fairly children will be randomly allocated so that everybody has an equal chance of either

receiving the mite impermeable bedding covers or receiving the placebo covers. Asthmatic children (3 - 17 years old) will be recruited following an exacerbation of asthma from hospitals across the North West Region. Research staff will visit them in their homes following recovery, consent them to the study and install the bedding covers. Children will be followed 3 monthly for a further 12 months by telephone contact. Questionnaires will collect infromation on exacerbations, symptoms and quality of life.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Exacerbation rate measured over 12 months from randomisation

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2011

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Children age 3-17 years with a physician diagnosis of asthma, following a recent exacerbation
2. Skin prick test positive to house dust mite (weal diameter 3mm or greater than the control)
3. Male or female participants

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 450; UK Sample Size: 450

Key exclusion criteria
1. Using mite proof bedding prior to enrolling in the study
2. Significant other medical condition

Date of first enrolment
01/11/2011

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust (UK)

Sponsor details
Education & Research Centre
Wythenshawe Hospital
Southmoor Road
Manchester
England
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M23 9LT

Sponsor type
Hospital/treatment centre

Website
http://www.south.manchester.ac.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
J P Moulton Charitable Foundation (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	15/07/2017		Yes	No