

# Preventing asthma exacerbations by avoiding mite allergen

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| <b>Submission date</b><br>25/07/2012   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/07/2012 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>13/03/2017       | <b>Condition category</b><br>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**  
Dr Clare Murray

**Contact details**  
University Hospital of South Manchester NHS Foundation Trust  
Education and Research Centre  
Wythenshawe Hospital  
Southmoor Road  
Manchester  
United Kingdom  
M23 9LT

## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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 information on exacerbations, symptoms and quality of life.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Exacerbation rate measured over 12 months from randomisation

### **Key secondary outcome(s))**



No secondary outcome measures

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

3 years

**Upper age limit**

17 years

**Sex**

All

**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**

United Kingdom

England

**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)

### ROR

<https://ror.org/00he80998>

## Funder(s)

### Funder type

Charity

### Funder Name

J P Moulton Charitable Foundation (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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 15/07/2017   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |