

# Can acute exacerbations of asthma be prevented with a four-fold increase in inhaled corticosteroid dose?

<b>Submission date</b> 28/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/07/2009	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
03/082

# Study information

## Scientific Title

## Study objectives

That acute exacerbations of asthma requiring oral corticosteroids can be prevented with pre-emptive treatment with a four-fold increase in the dose of inhaled corticosteroid.

## 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)

Prevention

## Participant information sheet

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

Asthma

## Interventions

Comparison of the effect of increasing regular inhaled corticosteroid four-fold to continuing on same dose in the event of increasing asthma symptoms.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Corticosteroids

## Primary outcome measure

The primary outcome will be the number of exacerbations requiring oral steroids in the active group compared with the placebo group.

### **Secondary outcome measures**

The total number of exacerbations and days with peak flow less than 15% baseline will also be compared. The sensitivity and specificity of our criteria to detect an exacerbation requiring prednisolone will be determined. The total dose of inhaled and oral corticosteroids used by both groups will be calculated.

### **Overall study start date**

01/04/2004

### **Completion date**

30/09/2006

## **Eligibility**

### **Key inclusion criteria**

1. Written Informed consent prior to participation in the trial
2. Male or female patients 16 years of age or older
3. Documented diagnosis of asthma
4. Treatment with 200 to 1000 mcg inhaled beclomethasone dipropionate or equivalent
5. At least one exacerbation requiring a temporary increase in inhaled corticosteroid or oral corticosteroids in the preceding 12 months
6. No oral corticosteroids for 4 weeks prior to or during the run-in period

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

500

### **Key exclusion criteria**

1. Other respiratory diagnosis or relevant medical condition
2. Smoking history of greater than 20 pack years
3. Subjects already using a management plan to deal with exacerbations and who would not wish to be randomised to placebo
4. Pregnant or nursing women

### **Date of first enrolment**

01/04/2004

### **Date of final enrolment**

30/09/2006

## Locations

### Countries of recruitment

England

United Kingdom

### Study participating centre

**Department Respiratory Medicine**

Nottingham

United Kingdom

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## Sponsor information

### Organisation

Nottingham City Hospital NHS Trust (UK)

### Sponsor details

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### Sponsor type

Hospital/treatment centre

### ROR

<https://ror.org/05y3qh794>

## Funder(s)

### Funder type

Charity

### Funder Name

Asthma UK (UK), ID 03/082

# 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	01/10/2009		Yes	No