

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

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

Contact name

Dr Timothy Harrison

Contact details

Department Respiratory Medicine
Nottingham City Hospital NHS Trust
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Department Respiratory Medicine

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

Nottingham City Hospital NHS Trust (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Asthma UK (UK), ID 03/082

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	01/10/2009		Yes	No