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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/11/2005	**Overall study status** Completed	
Last Edited 13/07/2009	**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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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