

# Inhaled fluticasone in acute severe asthma

<b>Submission date</b> 02/07/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/11/2007	<b>Condition category</b> Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
RES/10/2005

## Study information

**Scientific Title**

### Study objectives

High dose inhaled fluticasone is superior to standard treatment with intravenous hydrocortisone in patients with acute severe asthma.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

The study was approved by Christian Medical College Ethics committee on the 18th October 2005 (ref: IRB(EC)23/10/05).

## **Primary study design**

Interventional

## **Study design**

Randomised, double blind, double dummy, single centre, parallel group design.

## **Study type(s)**

Treatment

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

Acute severe asthma, acute exacerbation of asthma

## **Interventions**

Baseline Measurements:

Subjects, those who are randomised will be asked to perform baseline Peak Expiratory Flow (PEF) and Forced Expiratory Volume at one second (FEV1). Blood samples will be drawn for blood Theophylline level, pre-treatment serum potassium, Haemoglobin (Hb), Total Leucocyte Count (TLC), Differential Leucocyte Count (DLC) and Glucometer Random Blood Sugar (GRBS). Bedside Electrocardiogram (ECG) will be done before initiation of the treatment.

Drug dose, route and time of administration:

One group will receive two doses of Fluticasone 2 mg via nebulizer half an hour apart and single dose of intravenous (IV) placebo. The other group will receive single dose of Hydrocortisone 200 mg IV and two doses of placebo via nebulizer half an hour apart. In addition, all patients will receive salbutamol 2.5 mg and ipratropium bromide 0.5 mg via nebulizer alternating every 15 minutes for three hours.

Monitoring:

PEF and FEV1 to be measured at 0, 30, 60, 90, 120, 150 and 180 minutes from the time of administering the drug, for close monitoring of the patient although the primary outcome measurement is at 90th and 180th minute. If there is no improvement at 90th minute, the subject will be withdrawn from the trial and standard care will be given. If there is sign of worsening of the subject's condition from the baseline, at any point of time after the start of the trial, the subject will be immediately admitted into intensive care unit.

During the period of drug administration the patient will be continuously monitored for adverse effect. At the end of three hours serum potassium level and GRBS level will be assessed. At the end of three hours, those who fulfilled the discharge criteria will be discharged and the rest will be admitted in the ward for further management.

Follow up:

At the time of discharge, all subjects will be advised to take Tab. Prednisolone 30 mg Once Daily (OD) and Tab. Ranitidine 150 mg twice daily for seven days along with Metered Dose Inhaler (MDI) Salbutamol 100 mcg two puffs when necessary (PRN) and MDI Fluticasone 250 mcg two

puffs twice daily (BD) for one month. All of them will be advised follow up in Pulmonary Medicine Out-Patients Department (OPD) or Pulmonary Function laboratory at one month from the date of admission, to repeat PEF and FEV1.

If there is any aggravation of symptoms prior to the day of follow up, all patients are advised to report to the Emergency Department immediately.

### **Intervention Type**

Drug

### **Phase**

Not Specified

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

Fluticasone

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

FEV1 and PEF at 90 minutes and 180 minutes from the time of administering the drug.

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

1. Symptom assessment, at 90 minutes and 180 minutes from the time of administering the drug
2. Adverse effect of fluticasone at 90 minutes and 180 minutes from the time of administering the drug

### **Completion date**

30/05/2008

## **Eligibility**

### **Key inclusion criteria**

1. Age between 18 to 55
2. Asthma patients with Peak Expiratory Flow (PEF) and Forced Expiratory Volume in one second (FEV1) less than 50% of the predicted
3. Asthmatic for six months or more

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Not Specified

### **Sex**

Not Specified

### **Key exclusion criteria**

1. Underlying chronic lung disease
2. Fever more than 100.4°F

3. Smoker greater than five pack years
4. Patients with no legal representative or legal representative not willing to give consent
5. Life threatening asthma

**Date of first enrolment**

01/11/2006

**Date of final enrolment**

30/05/2008

## Locations

**Countries of recruitment**

India

**Study participating centre**

Department of Pharmacology

Vellore

India

632002

## Sponsor information

**Organisation**

Christian Medical College (India)

**ROR**

<https://ror.org/00c7kvd80>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Christian Medical College (India) - FLUID research grant (ref: R.C. Min No: 5735, RES/10/2005).

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration