ISRCTN96658320 https://doi.org/10.1186/ISRCTN96658320

Inhaled fluticasone in acute severe asthma

Submission date 02/07/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 12/07/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 09/11/2007	**Condition category** Respiratory	[ ] Individual participant data [ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. Symptom assessment, at 90 minutes and180 minutes from the time of administering the drug
2. Adverse effect of fluticasone at 90 minutes and180 minutes from the time of administering the drug

Overall study start date
01/11/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
110

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)

Sponsor details
Bagayam
Thorapadi Post

Tamil Nadu
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632002

Sponsor type
Government

Website
http://www.cmch-vellore.edu/

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

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