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Nebulised procaterol versus nebulised salbutamol for the treatment of moderate acute asthma

Submission date 23/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/08/2009	**Overall study status** Completed	
Last Edited 05/08/2009	**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
PMT-001/10/06

Study information

Scientific Title

The efficacy of nebulised procaterol versus nebulised salbutamol for the treatment of moderate acute asthma: a randomised, double-blind, parallel group study

Study objectives
The efficacy of nebule procaterol in improving peak expiratory flow rate (PEFR) in moderate acute asthma patients is superior to nebule salbutamol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical clearance and registration in local (Indonesian) regulatory authority approved 7th March 2006
2. Ethics Committee of the Medical Research Ethics of the Faculty of Medicine, University of Indonesia approved on 9th October 2006

Study design
Randomised double-blind two-arm parallel group phase III clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate acute asthma

Interventions
Treatment allocation was according to block randomisation using random permuted blocks of size 4. Patients received either one ampule of procaterol, diluted with 2 ml of normal saline, or one ampule of salbutamol three times every 20 minutes (at 0, 20 and 40 minutes). Both drugs were administered via jet-type nebuliser (Pulmoaid™). The PEFR was measured 20, 40, 60 and 120 minutes. At the same time, vital signs, asthma score and adverse events were evaluated. At 120 minutes, the blood gas analysis and the electrocardiogram (ECG) were repeated. Then, the patient was observed for adverse event(s) that might occur until 280 minutes. Afterwards, the patient was discharged from the study and received 6 tablets of bronchodilator (salbutamol) and 6 tablets of corticosteroid (methylprednisolone).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Procaterol, salbutamol, methylprednisolone

Primary outcome(s)
Difference from baseline in peak expiratory flow rate (PEFR). Measurements performed at 0, 20, 40, 60 and 120 minutes.

Key secondary outcome(s))
Difference from baseline in asthma score. Measurements performed at 0, 20, 40, 60 and 120 minutes.

Completion date
24/04/2008

Eligibility

Key inclusion criteria
1. Patients with moderate acute asthma according to Global Initiative for Asthma (GINA) 1998 (patients with asthma score 5 to 11; PEFR less than or same 80% predicted)
2. Patients of both genders, aged 15 to 60 years
3. Patients still have the ability to undergo examinations and give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnant and lactating women
2. Smokers
3. Patients with heart disease, hyperthyroidism, diabetes mellitus, chronic obstructive pulmonary disease (COPD) or other chronic diseases
4. Patients with signs of severe infections

Date of first enrolment
12/06/2007

Date of final enrolment
24/04/2008

Locations

Countries of recruitment
Indonesia

Study participating centre

Department of Pulmonology
Jakarta
Indonesia
13230

Sponsor information

Organisation
Otsuka Indonesia

ROR
https://ror.org/01ambd593

Funder(s)

Funder type
Industry

Funder Name
Otsuka Indonesia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration