

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2014/012

Scientific title of trial: Randomized controlled parallel arm clinical trial comparing the effectiveness, safety, cost and acceptability of salbutamol aerosol inhaler and salbutamol tablet in the management of acute exacerbation of bronchial asthma in children

Date of commencement (enrolment of first participant): 1st July 2014

Progression: 6 months 1 year 2 years 3 years

At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Due to annual transfers of the Co-PI Yes. The trial centres were expanded, and recruitment was stopped from the first centre.. ERC approval was obtained

Any changes to trial outcomes after commencement: None

2. Current status

Recruitment status: pending/ recruiting/ **recruitment complete**/ recruitment suspended / recruitment terminated

Number assessed for eligibility: One study site has not sent the last set of files

Number recruited and randomized: 102 (one study site has not sent the last set of files yet)

Number allocated to each intervention/arm: 51 each arm

Losses/exclusions after randomization: None

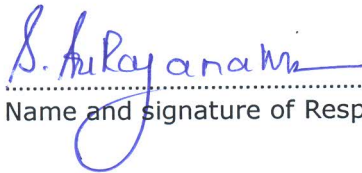
3. Trial output

Summary of Interim/Final data (if available): Of the 85 analysed: When measured using clinically relevant outcome indicators, there was no significant difference in effectiveness or safety between salbutamol tablet and salbutamol aerosol inhaler given through spacer as a symptom reliever in the treatment of mild-moderate acute asthma exacerbation in children aged 5-12 years

Presentations of results at scientific meetings: Presented at the 2016 scientific sessions of the SLMA

(Please attach a scanned copy or link to abstract)

Publications: Not yet
(Please attach a scanned copy or link to paper)



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Name and signature of Responsible Registrant/

30/9/16

Date: