

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2015/026

Scientific title of trial: Therapeutic evaluation of the antipyretic activity of the Ayurvedic preparation Sudarshana Suspension in febrile children.

Date of commencement (enrolment of first participant): 2015-11-05

Progression: 6 months 1 year 2 years 3 years

At completion ✓

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: pending/ recruiting/ recruitment complete: follow up continuing/
recruitment complete: follow up complete/ recruitment suspended / recruitment
terminated - Completed

Number assessed for eligibility: 43

Number recruited and allocated/randomized: 42

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: 21

Arm 2: 21

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: No

Arm 2: -01

3. Trial output

Date of trial completion ("last patient, last visit"): 22-06-2016

Final sample size: The initial sample size taken for the Phase II study was revised subsequently, with the advice of an expert on statistics. According to the revised power calculation, twenty one (21) children each were included in one group with approval from the Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura (ERC 18/15 and Date 14- 06 – 2016).

Sample size: 42 febrile Paediatric patients

The study was carried out in 2 groups, each group consisting of 21 patients.

Summary of Interim/Final data (if available):

Results

Forty-two paediatric febrile patients who entered the study provided valid post-baseline efficacy assessment and all available efficacy data were included in the analysis on the basis of intent to treat.

Demographic characteristics and baseline features

The treatment groups were comparable in age, gender and weight. In the *Sudarshana* suspension (SS) group (15 boys and 6 girls) the median age was 8.3 years (range 6- 12 years) and the median weight was 26.2kg (range 16.4 -38.2 kg). In the *Sudarshana* powder (SP) group (11 boys and 10 girls) the median age was 9.0 years (range 6-12 years), the median weight was 28.4 kg (range 18.5-38 kg). At entry, in the SS group there were 6 patients with a past history of wheezing and/or asthma; for the SP group there were 3 such patients.

Primary diagnosis of the condition

Most of the febrile children (14) were primarily diagnosed as having viral illnesses. Twelve febrile children were found to have mild upper respiratory symptoms. Seven febrile patients were found with skin rashes. Four patients had joint pain and two febrile children came with bruising of ankle and elbow joints due to trauma. Three patients had mild tonsillitis.

Efficacy data

The difference between treatments for the mean change from baseline in body temperature at six hours was 0.2°F. The maximum mean decrease from baseline in the temperature reduction during the first six hours of SS group was 1.5°F at fifth hour and in the SP group 1.3°F at same hour.

In the febrile children treated with SS, there was a significant ($p < 0.01$) decrease in the body temperature at 4th, 5th and 12th hour when compared to the SP group. It also showed ($p < 0.05$) significant reduction in the elevated body temperature at 2nd, 3rd, 24th, 54th, and 60th hours when compared with the Ayurveda standard drug group.

When overall efficacy was compared, it was revealed that the *Sudarshana* suspension, possesses significantly better antipyretic effect ($p < 0.05$) when compared with the traditional SP.

According to the findings, it was observed that the majority of the febrile children [Test group (SS):15 patients and control (SP): 09 patients] were afebrile within 2 days in both groups. Majority of the patients who had recovered had used 7 doses of *Sudarshana* suspension, whereas the 11 doses of SP were used by the majority of patients in SP group.

Haematological parameters of febrile children

All the patients included were tested for FBC, CRP and Dengue NS1 antigen before being included in the study. The haematological parameters (i.e. WBC, RBC, Hb, PCV, MCV, MCH, MCHC and platelets) showed no significant changes ($p > 0.05$) in the tested blood samples, compared to the normal values and all the patients (42) were reported negative in Dengue NS1 antigen tests.

Biochemical blood parameters

Acute effects of SS and SP were tested by measuring the key hepatic enzymes Alanine aminotransferase (ALT), aspartate aminotransferase (AST), Gamma-glutamyl transferase (Gamma-GT), alkaline phosphatase, Urea and Creatinine in serum on Day 1 and Day 3. There were no statistically significant ($p > 0.05$) differences in the serum parameters on Day 3 when compared with the baseline values (Day 1). These findings revealed that there were no possible toxic effects exerted by the novel drug in febrile children.

Palatability of *Sudarshana* suspension in febrile children

As for the palatability of the medication, it was found that the majority of the children took SS without any complaint after second dose of drug administration. There was a significant difference ($p < 0.001$) in palatability between SS and SP, where the suspension was found to be more palatable..

Other findings

Febrile children who were suffering from viral illnesses (14 patients), mild tonsillitis (3 patients) and joint pain (4 patients) were totally cured during the treatment period.

Children with skin rashes totally recovered from fever with oral treatments (SS-4 pts; SP-3 pts) .

In the 2 children with trauma, fever subsided within 3 days of treatment with (SS-1 pt and SP-1 pt.).

Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
Antipyretic effect of novel preparation <i>Sudarshana</i> suspension in febrile children	Weerakoon WASS, Perera PK, Gunasekara D. and Suresh TS: Antipyretic effect of novel preparation <i>Sudarshana</i> suspension in febrile children. 3 rd International Conference on Natural products Genomics and Drug Discovery; Colombo, Sri Lanka at Galadari Hotel, Colombo, Sri Lanka on 10 th -11 th July 2017;9 https://www.researchgate.net/publication/318350609_Antipyretic_effect_of_novel

Publications- No

Note: please include a URL link or scanned copy of the publication -

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)



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Name and signature of Responsible Registrant/
Principal Investigator

Date: 02-11-2020