Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2013/005**

Scientific title of trial: **Controlled trial on effect of Carica papaya leaf extract on patients with Dengue Fever**

Date of commencement (enrolment of first participant): **30st of July 2014**

Progression: **At completion**

1. Baseline data

Date of commencement: **1st of July 2014**

Any changes to the trial design/ methodology/ protocol after commencement: **Previously submitted**

Any changes to trial outcomes after commencement: **Previously submitted**

2. Current status : Recruitment complete

Number assessed for eligibility:

Number recruited and randomized: **160**

Number allocated to each intervention/arm: Treatment : **76** Control group : **84**

Losses/exclusions after randomization: **74**

3. Trial output

Summary of Interim/Final data (if available):

43 patients who consumed *carica papaya* leaf extract and 43 controls were selected according to chronological order of entry into the study. All patients were in the febrile phase at the time of entry into the study. There was no significant difference of clinical, biochemical or haematological parameters between the two groups at the entry of the study.

Mean systolic blood pressure, mean diastolic blood pressure, mean white blood cell count, mean platelet count and mean packed cell volume were compared between treatment and control groups and do not vary significantly between the two groups ($p > 0.05$).

Mean duration of the illness in treatment group 6.51 +/- 0.16 and in the control group 7.02 +/- 0.18. It is 0.5 day less in treatment group and it's statistically significant ($p < 0.05$). Mean duration of fever in the hospital in treatment group 1.67 +/- 0.21 and in the control group 3.09 +/- 0.27. It is 1.5 days less in treatment group and it's statistically significant ($p < 0.001$). Mean duration of hospital stay in treatment group 3.70 +/- 0.16 and in the control group 4.70 +/- 0.22. It is one day less in treatment group and it's statistically significant ($p < 0.001$). Mean duration of illness from entry into study to discharge in treatment group 2.95 +/- 0.15 and in the control group 3.63 +/- 0.24. It is 0.5 day less in treatment group and its statistically significant ($p < 0.05$).

Only two patients led to pleural effusion in treatment group and 10 patients led to pleural effusion in control group (Chi sq. 6.20, p value 0.013). Hence development of pleural effusion / dengue haemorrhagic fever is significantly lower (p value < 0.05) in treatment group.

Presentations of results at scientific meetings:

Publications:

Dr. Sanath Hettige

(Principle Investigater)

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Name and signature of Responsible Registrant Date: **04.09.2015**