

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/ 2015/ 012

Scientific title of trial: Effects of Vitamin E Supplementation on the clinical outcome of Dengue Fever and Dengue Haemorrhagic Fever in Children

Date of commencement (enrolment of first participant): 01.08.2015

Progression: 6 months 1 year 2 years 3 years

At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

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

Number assessed for eligibility: 220

Number recruited and randomized: 127

Number allocated to each intervention/arm: Treatment 61 Control 66

Losses/exclusions after randomization: None

3. Trial output

Summary of ~~Interim~~/Final data (if available):

The temporal distribution patterns of WBC, platelets, serum albumin and serum cholesterol were higher, while PCV, serum AST and ALT levels were lower in the treatment group compared to placebo. PCV on day 3.5, WBC on day 6, ALT on day 4 and 5, AST on day 3 to 5 and albumin on day 5 were significantly improved in the treatment group. There was no difference in the duration of hospital stay or occurrence of leaking. However, the duration of leaking was significantly lower in the treatment group.

Presentations of results at scientific meetings:

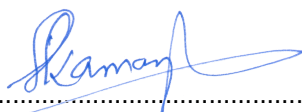
1. The 6th Congress of the European Academy of Paediatric Societies – EAPS 2016, Geneva, Switzerland | October 21-25, 2016.

<http://eaps16.kenes.com/EAPS16/CM.NET.WebUI/CM.NET.WEBUI.scpr/SCPRfunctiondetail.aspx?confID=05000000-0000-0000-0000-0000000000188&sesID=05000000-0000-0000-0000-0000000037270&absID=07000000-0000-0000-0000-0000000181069>

2. Chathurangana PWP, Samaranayake DBDL, Quieters VG, Wickramasinghe VP. Can vitamin E supplementation modify the outcome of dengue fever and dengue haemorrhagic fever in children? SLCP 2016, 19th Annual Scientific Congress. FP19 **(Professor Zef Ibrahim award for the best paper in tropical paediatrics)**

(Please attach a scanned copy or link to abstract)

Publications: Manuscript has been submitted to Asian Pacific Journal of Tropical Disease
(Please attach a scanned copy or link to paper)



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Name and signature of Responsible Registrant/

Date: 25th July 2017