

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2013/024

Scientific title of trial: Randomized, double-blind, controlled, comparative study on intralesional 10% and 15% hypertonic saline versus intralesional sodium stibogluconate in Leishmania donovani cutaneous leishmaniasis

Date of commencement (enrolment of first participant): 8 August 2013

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: 503

Number recruited and randomized: 444

Number allocated to each intervention/arm: SSG 170/ 10HS 192/ 15HS 82

Losses/exclusions after randomization: 17

3. Trial output

Summary of Interim/Final data (if available):

Presentations of results at scientific meetings:

(Please attach a scanned copy or link to abstract)

Publications:

(Please attach a scanned copy or link to paper)

Ranawaka RR, Weerakoon HS, de Silva SH. Randomized, double-blind, controlled, comparative study on intralesional 10% and 15% hypertonic saline versus intralesional sodium stibogluconate in Leishmania donovani cutaneous leishmaniasis. Int J Dermatol. 2015 Jan 20. doi: 10.1111/ijd.12685. [Epub ahead of print] PMID: 25600472

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Name and signature of Responsible Registrant/

14.09.2015
Date: