

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2016/015

Scientific title of trial: A Phase II dose finding study in Hypnale spp with New Polyvalent Snake Antivenom (ICP-AVRI-UOP Sri Lanka polyspecific antivenom)

Date of commencement (enrolment of first participant): 04-Dec-2016

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. As mentioned in the original protocol we have recruited patients for the first two groups (patients who will receive 2 vials and 5 vials of the Sri Lankan Antivenom) and the samples were analyzed. As the results of the analysis show complete venom neutralization in all subjects, it was decided not to increase the antivenom dose to 7 or 10 vials per patient. Instead, it has been decided to run the trial with a new dosing level for a group of 20 patients who will receive 1 vial of Sri Lankan antivenom each.

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: recruitment complete

Number assessed for eligibility: 131

Number recruited and allocated/randomized: 71

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

Arm 1: 2 vials each for 21 subjects

Arm 2: 5 vials each for 21 subjects

Arm 3: 1 vial each for 29 subjects

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

Arm 1: 1 subject

Arm 2: 1 subject

Arm 3: 9 subjects

All samples have been analysed and currently the study is at data analysis stage.

3. Trial output

Date of trial completion ("last patient, last visit"): 21/04/2018

Final sample size: 60

Summary of Interim/Final data (if available):

The new Sri Lankan antivenom appeared to bind all free antivenom at both doses in patients with confirmed hump-nosed viper bites.

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).
In vivo efficacy and pharmacokinetics of a new Sri Lankan antivenom for Hump-nosed Viper (<i>Hypnale</i> spp) bites – A preliminary dosing study	Mirajkar N, Premathilake R, Gutierrez J M, Gawarammana I, Isbister G. In vivo efficacy and pharmacokinetics of a new Sri Lankan antivenom for Hump-nosed Viper (<i>Hypnale</i> spp) bites – A preliminary dosing study. "16th Annual Scientific Congress of Asia Pacific Association of Medical Toxicology (APAMT) 8–10 November 2017, Kandy, Sri Lanka." http://www.sactrc.org/wp-content/uploads/2018/01/16th Oral Presentation 01.pdf

Publications

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)

Name and signature of Responsible Registrar/
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Date: 27/07/2020