

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2017/021

Scientific title of trial: **A multi-center, double-blind, randomized, 24-month study, to compare the efficacy of doxycycline once daily for 6 weeks versus placebo in improving filarial lymphedema independent of active filarial**

Date of commencement (enrolment of first participant): 16.02.2018

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
Version 3 is annexed with its ERC approval.

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: 251

Number recruited and allocated/randomized: 197

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

Arm 1 (Group A – lymphoedema Grade 1-3): 181

Arm 2 (Group B – lymphoedema Grade 4-6): 16

Losses/exclusions after allocation/randomization:

Arm 1(Group A – lymphoedema Grade 1-3):3

Arm 2(Group B – lymphoedema Grade 4-6):0

3. Trial output

Summary of Interim/Final data (if available):

1st DSMB report is annexed for your kind perusal.

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).

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)



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Name and signature of Responsible Registrant/

Date: 22/05/2018

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