Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2020/011

Scientific title of trial: Hydroxychloroquine for Post-Exposure Prophylaxis of COVID-19 among naval personnel in Sri Lanka: study protocol for a randomized controlled trial

Date of commencement (enrolment of first participant):

 Progression:
 6 months ⊠
 1 year □
 2 years □
 3 years □

 At completion □

 3 years □

 3 years □

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: None

Any changes to trial outcomes after commencement: None

2. Current status

Recruitment status: pending/ recruiting/ recruitment complete: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 500

Number recruited and allocated/randomized: 402

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

Arm 1: **202** Arm 2: **200**

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

Arm 1: **60** Arm 2: **59**

3. Trial output

Date of trial completion ("last patient, last visit"): 06.06.20

Final sample size: 283

Summary of Interim/Final data (if available):

402 of the 500 sailors invited agreed to participate. However, only 283/402 (70.4%) completed the trial. Even among them, only 214/283 (75.6%) had taken the full course of prescribed trial medicine, well below the required sample size to power the study (n=396). We did not attempt an analysis of the outcome. **Trial was abandoned.**

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)
Hydroxychloroquine for Post-Exposure Prophylaxis of COVID-19 among naval personnel in Sri Lanka: study protocol for a randomized controlled trial	Under revision for consideration in "Trials" journal https://www.researchsquare.com/article/rs-28949/v1

Name and signature of Responsible Registrant/ Principal Investigator

Date: 02.07.20