

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2019/016

Scientific title of trial: Formulation and evaluation of the antimicrobial efficacy of novel alcohol based and non-alcohol based natural hand scrubs with medicinal plant extracts

Date of commencement (enrolment of first participant): 02.06.2019

Progression: 6 months 1 year 2 years 3 years

At completion ✓

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement:

According to the results of the in-vitro antimicrobial efficacy test conducted by using agar well diffusion method and stability tests, **only** the most active and stable three alcohol-based herbal hand scrub formulations (F₁- Arm 1, F₃ – Arm 3 & F₅ – Arm 5) out of five and most active and stable two non-alcohol-based herbal hand scrub formulations (F₁ – Arm 6 & F₃ – Arm 8) out of six were selected for clinical trials to evaluate before application, 10 seconds and 15 seconds after application on the fingertip of the healthy human volunteer. The same procedure given in the original document has been conducted for 1st day of preparation, after 15th and 30th days.

Any changes to trial outcomes after commencement: No

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: 107

Number recruited and allocated/randomized: 450

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

Arm 1- Alcohol based hand scrub formula 1 on right thumb (N=30) Negative control on left thumb (N=15) and positive control on left thumb (N=15 each)

Arm 3 - Alcohol based hand scrub formula 3 on right thumb (N=30) Negative control on left thumb (N=15) and positive control on left thumb (N=15 each)

Arm 5 - Alcohol based hand scrub formula 5 on right thumb (N=30) Negative control on left thumb (N=15) and positive control on left thumb (N=15 each)

Arm 6 – Non-alcohol based hand scrub formula 1 on right thumb (N=30) Negative control on left thumb (N=15) and positive control on left thumb (N=15 each)

Arm 8 - Non-alcohol based hand scrub formula 3 on right thumb (N=30) Negative control on left thumb (N=15) and positive control on left thumb (N=15 each)

As above this clinical trial has been conducted for 1st day of preparation, after 15th and 30th days.

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

Arm 1,3,5,6,8 :N/A

3. Trial output

Date of trial completion ("last patient, last visit"): 17.12.2019

Final sample size: 30

Summary of Interim/Final data (if available):

Annexure 01 shows the results of in-vivo antimicrobial efficacy of Arm 1, Arm 3, Arm 5, Arm 6, Arm 8 for 1st day, 15th day and 30th day respectively. Annexure 02 shows results of self-administered questionnaire of Arm 1, Arm 3, Arm 5, Arm 6, Arm 8.

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).
Not yet published	

Publications

Note: please include a URL link or scanned copy of the publication

It has been presented the outcomes of the above clinical trials at the Progress review sessions held by the Faculty of Graduate Studies, University of Ruhuna on 14th December 2019.

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
In process	



Ms. K.D.S.V. Karunanayaka

Name and signature of Responsible Registrant/
Principal Investigator

Date: 18.01.2020