

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2024/009**

Scientific title of trial: Effectiveness of Dry Needling for Improving Pain and Disability in Adults with Migraine Headache; A Randomized Controlled Trial

Date of commencement (enrolment of the first participant): 15th March 2024

Progression: 6 months 1 year 2 years 3 years

At completion

1. Baseline data

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

- Sample size re-estimation was done with the justification due to the inadequate number of patients with migraine headache according to the inclusion criteria. (The ethical approval letter for the amendment is attached with this report)
- According to the adjusted calculation of sample size, the total sample size is 34 (17 patients for each treatment arm and control arm)
- Data analysis will be done using paired t-tests and matched pairs.

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: 282

Number recruited and allocated/randomized: 34

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

Arm 1: 17

Arm 2: 17

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

Arm 1: 1

Arm 2: 5

3. Trial output

Date of trial completion ("last patient, last visit"): 30th August

Final sample size: 28

Summary of Interim/Final data (if available):

--

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)



.....
HMMD Herath

(Name and signature of Principal Investigator)

Date: 15.09.2024