Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2021/029

Scientific title of trial: A single arm phase II clinical trial to assess safety, efficacy and feasibility of Polyethylene Glycol (PEG) fusion in nerve repair following acute transection of median and/or ulnar nerves in adults

Date of commencement (enrolment of first participant): 30. 10. 2021

Progression: 6 months ☒ 1 year ☐ 2 years ☐ 3 years ☐

At completion ☐

1. Baseline data

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

Operating technique was improved by the surgeons. It was identified that exact orientation of the nerve fascicles is required to demonstrate nerve fusion intra-operatively and for better results (not-analysed, only observational) . Therefore, modification of the technique of neurorraphy (whether to perform fascilcular suturing) is being considered by the investigators.

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: 07

Number recruited and allocated/randomized: 05

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

Losses/exclusions after allocation/randomization (please edit as relevant): 01

Due to the crisis situation in the country adherence to the protocol has become not practical due to reasons such as lack of resources (e.g. limitation of anaesthetic agents and therefore opting to local or regional anaesthetic techniques and limited availability of ideal suture materials) and patients not attending regular follow up sessions due to transport issues. Therefore, investigators are compelled to temporary suspend the recruitment of the participants to maintain the integrity of the methodology. For the same reasons it will be necessary to extend the study period and we request SLCTR to provide appropriate approval as required in the future.

3. Trial output

Date of trial completion ("last patient, last visit"): N/A

Final sample size:

Summary of Interim/Final data (if available):

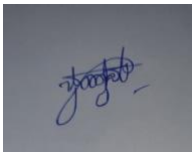
Interim analysis was planned after recruitment of 10 participants have completed 12 weeks of follow up and therefore, it is not done yet.

Abstract presentations of results at scientific meetings. N/A
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 N/A
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)**



Dr Jeewan Pradeep Rankothkumbura
……..
Name and signature of Responsible Registrant/
Principal Investigator

Date: 03. 07. 2022