Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2020/003 Scientific title of trial: Comparative effectiveness and maternal acceptability with cervical ripening using membrane sweep vs cervical cerclage: A randomized controlled clinical trial Date of commencement (enrolment of first participant): 20th February 2020 Progression: 6 months □ 1 year □ 3 years □ 2 years □ At completion ✓ 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: 349 Number recruited and allocated/randomized: 312 Number allocated/randomized to each intervention/arm (please edit as relevant): Group S (Membrane Sweep): 104 Group M (Cervical massage): 106 Group C (Control – Neither Membrane sweep nor cervical massage): 102 Losses/exclusions after allocation/randomization (please edit as relevant): Group S (Membrane Sweep): 4 Group M (Cervical massage): 6 Group C (Control) : 2

3. Trial output

| Date of trial completion ("last patient, last visit"): 4/07/2020 | |
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| Final sample size: 300 | |
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| Summary of Interim/Final data (if available): | |
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| Abstract presentations of results at scientific meetings Note: please include a URL link or scanned copy of the abstract | |
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| litie of Abstract | Full citation (please include authors, date, title of conference and place of presentation, page number of abstract). |
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| Name and signature of Responsible Registrant/ Principal Investigator | |

Date: 27/7/2020