

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **2013/30**

Scientific title of trial: **Outpatient cervical ripening with the nitric oxide donor isosorbide mononitrate vaginally , in uncomplicated singleton pregnancies at 39 weeks gestation: a double blind randomized controlled trial**

Date of commencement (enrolment of first participant): **01 October 2013**

Progression: 6 months 1 year 2 years 3 years

At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: **No**

Any changes to trial outcomes after commencement: **No**

2. Current status

Recruitment status: pending/ recruiting/ **recruitment complete**/ recruitment suspended / recruitment terminated

Number assessed for eligibility: **565**

Number recruited and randomized: **144**

Number allocated to each intervention/arm: **72**

Losses/exclusions after randomization: **One in the treatment arm. Included in an intention to treat analysis for the primary outcome but excluded from the analysis of the secondary outcomes**

3. Trial output

Summary of Interim/Final data (if available):

Presentations of results at scientific meetings:

This work was presented as a free oral communication at the FIGO-SAFOG-SLCOG Conference held in Colombo in October / November 2014 and published as an abstract in the Sri Lanka Journal of Obstetrics & Gynaecology 2014;36(Suppl 1): FC 10.5, Pg 28 and also presented as e poster at the British Congress of Obstetrics & Gynaecology in the UK in 2015

(Please attach a scanned copy or link to abstract)

Publications: **A full paper has been submitted to the Ceylon Medical Journal for consideration of publication**

(Please attach a scanned copy or link to paper)



Professor Malik Goonewardene

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Name and signature of Responsible Registrant/

Date: **23.08.2016**