

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **2010 / 09**

Scientific title of trial: : **Efficacy of two different treatment regimens of vaginal nitric oxide donor (Iso-sorbide mononitrate) used for pre induction cervical ripening : A randomized controlled trial**

Date of commencement (enrolment of first participant):

Progression: 6 months 1 year 2 years 3 years

At completion X

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: **270**

Number recruited and randomized: **225**

Number allocated to each intervention/arm: **75, 75, 25**

Losses/exclusions after randomization: **The outpatient treatment arm had to be discontinued pre maturely due to heavy monsoon rains and floods in southern providence of Sri Lanka over three months, during the study. This resulted in only 25 participants being allocated to the outpatient arm. One patient in the two day treatment arm and eight patients in the three day treatment arm could not complete the treatment schedule on account of obstetric complications unlikely to be associated with the interventions**
This resulted in 74,67 & 25 completing the treatment

3. Trial output

Summary of Interim/Final data (if available):

The three day inpatient regimen of 60 mg of the sustained release form of Iso-sorbide Mononitrate vaginally was better than the two day regimen. Although the effectiveness of the outpatient regimen could not be properly estimated, the side effects appeared to be better tolerated with outpatient therapy

Presentations of results at scientific meetings:

This work was presented as a free oral communication at the 45th Annual Scientific Sessions of the SLCOG and published as an abstract in the Sri Lanka Journal of Obstetrics & Gynaecology 2012;34(Suppl 1): OP 13, pg 81

<http://sljog.sljol.info/articles/abstract/10.4038/sljog.v34i5.4891/>

(Please attach a scanned copy or link to abstract)

Publications: **A full paper is being prepared for submission 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: **06.09.2016**