

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2015/007

Scientific title of trial: A Randomized Controlled Trial to compare the effectiveness of cyproterone acetate /ethinyl estradiol, desogestrel / ethinyl estradiol and metformin on improving hirsutism, hormonal and metabolic features of polycystic ovary syndrome.

Date of commencement (enrolment of first participant): 20/04/2015

Progression: 6 months 1 year 2 years 3 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/ recruitment suspended / recruitment terminated - recruiting

Number assessed for eligibility: 96

Number recruited and randomized: 69

Number allocated to each intervention/arm:

Arm	Drugs	Number allocated to each intervention/arm:
1	2 mg of cyproterone acetate and 35 microg of ethinyl estradiol pill daily placebo pill equal to Metformin SR pill daily placebo pill equal to desogestrel 0.15mg/ ethinyl estradiol(20 microg) pill daily	20
2	desogestrel 0.15mg/ ethinyl estradiol(20 microg) daily placebo pill equal to metformin SR pill daily	18

	placebo pill equal to 2 mg of cyproterone acetate and 35 microg of ethinyl estradiol pill daily	
3	metformin (SR) daily 2 mg of cyproterone acetate and 35 microg of ethinyl estradiol daily placebo pill equal to desogestrel 0.15mg/ ethinyl estradiol(20 microg) pill daily	13
4	metformin(SR) daily desogestrel 0.15mg/ ethinyl estradiol(20 microg) daily placebo pill equal to 2 mg of cyproterone acetate and 35 microg of ethinyl estradiol pill daily	18

Losses/exclusions after randomization: 4

3. Trial output

Summary of Interim/Final data (if available): no

Presentations of results at scientific meetings: no

(Please attach a scanned copy or link to abstract)

Publications:

(Please attach a scanned copy or link to paper) - no

Sanjeet
Dr. Sanjeetani Fonseca
 Name and signature of Responsible Registrant/

11/09/2015

Date: