

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2015/007

Scientific title of trial: 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: not changed

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: 156

Number recruited and randomized: 117

Number allocated to each intervention/arm:

Arm	Drugs	No of patients
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	28
2	desogestrel 0.15mg/ ethinyl estradiol(20 microg) daily	27

	<p>placebo pill equal to metformin SR pill daily</p> <p>placebo pill equal to 2 mg of cyproterone acetate and 35 microg of ethinyl estradiol pill daily</p>	
3	<p>metformin (SR) daily</p> <p>2 mg of cyproterone acetate and 35 microg of ethinyl estradiol daily</p> <p>placebo pill equal to desogestrel 0.15mg/ ethinyl estradiol(20 microg) pill daily</p>	26
4	<p>metformin(SR) daily</p> <p>desogestrel 0.15mg/ ethinyl estradiol(20 microg) daily</p> <p>placebo pill equal to 2 mg of cyproterone acetate and 35 microg of ethinyl estradiol pill daily</p>	30

Losses/exclusions after randomization: 6

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)

Sanjeev
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Name and signature of Responsible Registrant/

28/09/2017
Date: