

Sample and Data Collection Procedures

During the participation in this study, the participants will have a total of 12 visits. They will begin with a screening visit to determine if they are eligible for study participation. Following screening they will have a baseline visit to receive their study medications. Following baseline, they will have a total of 5 monthly visits and an end of treatment visit. Below is a brief chart explaining the visits and procedures to be completed for study.

Procedures	Screen	Baseline	Midluteal MV#1-5	Menses MV#1-4	End of Treatment
Sign Consent	X				
Complete questionnaires	X				X
Urine pregnancy test	X	X	X		X
Height & BMI	X				X
Weight	X	X	X		X
Vital signs	X	X	X		X
Hip & Waist measurements	X				X
Acne score	X				X
Sebumeter score	X		X		X
Hirsutism score	X				X
Blood work for male & female hormones	X				
Blood work for progesterone	X	X	X		X
Blood work for pregnancy	X	X	X	X	X
Blood work for Safety Labs	X				X
Blood work for study DNA		X			
Blood work for central core lab	X	X	X		X
Rubella, Varicella & HIV screen	X				
Blood work for repository		X			
Complete physical exam & pap smear	X				
Transvaginal ultrasound	X	X	X		X
Sonohysterogram or Hysterosalpingogram	X				
Semen Analysis	X				
Dispensed study meds		X	X		
Collect study meds			X		
Dispense daily journals		X	X		
Collect daily journals			X		X
Assess adverse events and concomitant meds			X		X