The United States continues to have the highest rate of adolescent pregnancy in the developed world. Among sexually active adolescent girls, the use of effective contraception is crucial to prevent pregnancy. Depot medroxyprogesterone acetate (DMPA) is an effective hormonal birth control that is frequently prescribed to adolescent girls. Despite its many advantages, DMPA continuation rates are low in adolescents. Side effects, namely weight gain and bone mineral density (BMD) loss, are common reasons for discontinuation of this method and have far-reaching health implications for adolescent DMPA users. The goal of this study was to improve the safety profile of DMPA in adolescents through minimization of drug exposure and evaluation of associations between medroxyprogesterone acetate (MPA) exposure and weight gain and BMD loss.

A single-blind, prospective, randomized controlled trial of three doses of DMPA was conducted to identify an optimal dose that minimizes total exposure to medroxyprogesterone acetate (MPA) while maintaining uncompromised (e.g. virtually 100%) contraceptive efficacy. The study cohort consists of adolescent females age 12-21 who were randomly assigned to the following three DMPA dose arms: 150mg IM every 12 weeks; 104mg IM every 12 weeks; and 75mg IM every 12 weeks. Currently, 9 subjects have been randomized to the 75 mg dose cohort, 9 to the 104 mg dose cohort, and 8 to the 150 mg dose cohort. Although SFP funding has ceased, we will continue enrollment until we reach 15 subjects per arm dose cohort.

All subjects, regardless of DMPA dose, were followed for 48 weeks from time of enrollment. BMI was assessed at 0, 12, 24, 36, and 48 weeks. BMD of the lumbar spine (LS), total hip (TH), and femoral neck (FN) was measured at 0, 24, and 48 weeks. Serum MPA, estradiol and progesterone concentrations were obtained at baseline and then weekly between the first and second DMPA injection (0 – 12 weeks), monthly between the second and third DMPA injection (16, 20, 24 weeks), and then at the end of the remaining 12-week dosing intervals (36 and 48 weeks).

Our study has established the feasibility of enrolling adolescents as young as 12 years of age in contraceptive clinical trials. Furthermore, we have shown that lower doses of DMPA provide effective contraception for 12 weeks.

Interim analyses show a significant correlation between maximum MPA concentration and BMI. Preliminary outcome data show differences between groups with regards to measures of weight gain and BMD loss. However, we will remain blinded to group dose assignments until completion of data collection. Group comparisons will be performed after 15 subjects per dose arm have completed the study.