Use of Norethindrone Acetate for Management of Bleeding Associated With the Etonogestrel Contraceptive Implant

NCT02353247
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Data Analysis Plan

The primary hypothesis was analyzed using repeated measures ANOVA (RM-ANOVA) with two groups and three measurements (summary statistics at day-90, day-180, and day-270). To have at least 80% *a-priori* power to detect a medium effect size ($f = 0.25$) at alpha $= 0.05$, a total sample size of 28 was required with approximately equal sized groups. (G*Power version 3.1.9.2[1]; Faul, Erdfelder, Lang, & Bucher, 2007). Anticipating and reacting to high attrition rates, 72 participants were enrolled.

Data cleaning and management was done to identify participants who responded to daily SMS surveys at least 189 times (70% of the 9-month trial). Fifteen (21%) of the 72 participants provided fewer than 100 responses. Another 14 participants (19%) provided between 100 and 188 responses. An additional four participants (9.7%) were removed because they did not respond at least 70% of the days during each 90-day time period. The final data set consisted of 39 participants: 18 in the No Intervention arm and 21 in the Intervention arm. Post-hoc analysis indicated the study was powered at 93%.

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[1] NOTE:  Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, *39*, 175-191.

Data collection was done with Qualtrics™ (Provost, Utah) and analyses were done using Microsoft Excel (Redman, Washington) and IBM SPSS Statistics for Macintosh (version 24, Chicago, Illinois).