Objective: This was a single-arm, open-label phase 1 study with a primary objective of assessing ovulation inhibition and ovarian activity in women receiving an extended-regimen combined oral contraceptive (COC). Our objective here is to report data on restoration of ovulatory capacity in women enrolled in this study after completion of one 91-day extended cycle.

Method: Healthy, ovulatory women with body mass index $\geq 18$ to $<30$ kg/m$^2$ received 1 extended-cycle COC regimen consisting of 84 days of 150 mcg LNG/30 mcg EE tablets, followed by 7 days of 10 mcg EE tablets. Ovulation suppression was documented as previously reported [1]. Return to ovulation was assessed on Day 18, 19, or 20 of the post-treatment cycle. Serum progesterone (PGN) level $\geq 15.9$ nmol/L (5 ng/mL) was used as an indicator of whether ovulation had returned after ovarian suppression.

Results: Of 45 total subjects treated, 35 subjects were included in the efficacy cohort (mean age: 27.6±3.8 years). Subjects were excluded from the efficacy cohort if they took fewer than 84 days of treatment, missed consecutive or $>2$ tablets, or missed consecutive or $>3$ study procedures. As previously reported [1], administration of this 91-day COC regimen reduced ovarian activity and follicle development, and ovulation suppression was achieved in 33 of 35 subjects. Mean PGN level was 29.7 nmol/L in the pretreatment cycle; PGN levels were generally low (1.8-3.1 nmol/L) during treatment. As assessed by serum PGN $\geq 15.9$ nmol/L within 32 days after completing the last tablet in the extended-regimen COC, ovulation returned in 27 of 35 subjects (77.1%; 95% CI: 59.9, 89.6).

Conclusion: Evidence of ovulatory activity returned within 1 month in most subjects following cessation of treatment with this 91-day extended-regimen COC.


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