

Ovulation Suppression and Cycle Control of Ethinyl Estradiol and Levonorgestrel Combination Patches

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ABSTRACT

Objective or purpose of the study: To evaluate ovulation suppression (OS), cycle control, and safety of three transdermal contraceptive delivery systems (TCDS) containing differing amounts of LNG and EE; assess patch tolerability/wearability.

Methods used for data collection: The multi-center, open-label, randomized three cycles study evaluated 123 women with regular cycles using either Agile TCDS: AG200LE, AG200 and AG200-15 delivering LNG from 75 to 100 ug daily and EE from 15 to 30 ug daily. Serum-progesterone was measured on days 1, 8, 11, 15, 19, 22 and 25. EE and LNG were determined on days 8, 15 and 22. Probable ovulation was defined as two consecutive serum progesterone levels above 4.6 ng/ml. Daily diary cards were used.

Result summarized: For the intent to treat population (ITT) wearing AG200LE, AG200 or AG200-15, OS was 72.8%, 88.4% and 90.4% respectively. For the ITT with verifiable compliance, OS was 75.0%, 90.4% and 92.3% respectively. EE influenced LNG pharmacokinetics and pharmacodynamics. No serious adverse events observed. The AG200-15 showed good cycle control with 85% women reporting no breakthrough bleeding/spotting in cycle 3 compared to 71% in the AG200LE and AG200 groups. Skin irritation occurred for 2% of all patches and was mild. Incidence of patch fall-off or detachment were <1% in cycle 3.

Conclusions reached: AG200-15 is the optimal formulation for OS and cycle control and with hormone exposure equivalent to oral doses of approximately 100 µg LNG daily and approximately 30 µg EE daily.