Abstract Id: 8840
Oral presentation on Friday Oct 18th 11.45-13.15 session «Contraception»

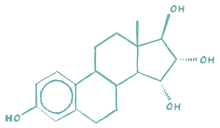
Contraceptive Efficacy and Bleeding Pattern of a New COC containing Estetrol 15 mg and Drospirenone 3 mg - Phase 3 Trial Results

Authors: Mitchell D. Creinin[1], Marie Mawet[2], Sophie Ledant[2], Maud Jost[2], Jean-Michel Foidart[2,3]

[1] *Department of Obstetrics and Gynecology, University of California, Davis; Sacramento, CA, USA*

[2] *Mithra Pharmaceuticals, Liège, Belgium*

[3] *University of Liège, Liège, Belgium*



Objective: To assess the contraceptive efficacy and safety, over up to 1 year of use, of estetrol (E4) 15 mg / drospirenone (DRSP) 3 mg in a 24/4-day regimen.

Methods: This multicentre, open-label, phase 3 trial was conducted in 69 centers across Europe and Russia. Healthy women 18-50 years old with regular cycles and a BMI ≤35.0 kg/m^2 enrolled for up to 13 consecutive cycles. Subjects recorded daily pill intake, other contraceptive method use, and bleeding/spotting episodes on a daily diary. Follow-up evaluations were scheduled after 2, 4, 7, 10, and 13 cycles. The primary efficacy endpoint was on-treatment pregnancies in women 18-35 years old measured by the Pearl Index (PI) in at-risk cycles (with no other contraceptive use). Secondary outcomes included bleeding patterns, safety (adverse events [AEs], routine laboratory parameters, vital signs, and physical exam findings).

Results: Five on-treatment pregnancies occurred of which 3 were considered user failure. The Pearl Index calculated from the 1,343 subjects with 14,759 at risk cycles was 0.44 (95% CI: 0.14 – 1.03). The method failure PI was 0.26 (95% CI: 0.05-0.77). Withdrawal bleeding generally occurred from Day 26 to Day 3 of the next cycle in 91.9% to 94.4% of subjects. The mean number of scheduled bleeding and/or spotting days decreased from 6.1 days at Cycle 1 to 5.3 days at Cycle 2 and ≤5 days from Cycle 4. Approximately half the number of bleeding and/or spotting days were just spotting. The incidence of unscheduled bleeding and/or spotting episodes decreased notably from Cycle 1 (23.5% of subjects) to Cycle 2 (19.2%), and decreased further to 12.8 % at Cycle 12. Less than 1.5% of subjects had only unscheduled bleeding in any cycle. Unscheduled bleeding and spotting was of short duration (mean 0.1 day and <0.5 day, respectively). No relevant changes were observed in any physical exam findings or haematology, biochemistry, or lipid profile parameters. The most common study medication related treatment emergent adverse events (TEAEs) were metrorrhagia (4.9%), vaginal bleeding (4.2%), acne (3.8%), and headache (2.6%). Discontinuation rate due to drugrelated TEAEs was 9.1%.

Conclusion: E4 15 mg / DRSP 3 mg shows high contraceptive efficacy and excellent cycle control, with withdrawal bleeding/spotting in >92% of cycles typically lasting <5 days. The treatment is well-tolerated with no known safety concerns for a combined oral contraceptive.

mithra
Women's Health