



Dydrogesterone for Dysmenorrhea Treatment

SCIENCE

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Key Take-Away:

This study confirmed the evidence that dydrogesterone effectively reduced dysmenorrhea pain symptoms and did not repress ovulation during oral administration. This is the 1st study to establish that dydrogesterone is the only hormonal drug which can be permitted to get pregnant during its administration. It also renders efficacy and safety for the treatment of endometriosis with dysmenorrhea.

Introduction:

The efficacy and safety of dydrogesterone in Japanese women suffering from dysmenorrhea has been evaluated in this study.

Methods:

This is an open-label, single-arm, multicenter study. One dydrogesterone 5 mg tablet was administered orally twice daily (BID) for 21 days, starting from 5th to 25th day of every menstrual cycle. Total 44 (safety analysis) and 31 patients (efficacy analysis) were enrolled in this study. Overall dysmenorrhea score, dysmenorrhea subscale scores, dysmenorrhea visual analog scale, low back pain, headache, the severity of menstruation-related lower abdominal pain, and nausea/vomiting, basal body temperature, and the serum estradiol and progesterone levels were examined.

Results:

Baseline of the overall dysmenorrhea score was 4.61, which went down over time after the administration of dydrogesterone. This decrease was statistically significant at and after the 2nd cycle of menstruation. The mean change from baseline at the final evaluation point was -1.84 ($P < 0.001$). The intensity of menstruation-related lower abdominal pain, low back pain, headache, and nausea/vomiting proved to decrease over time in the evaluated menstruation cycles. Basal body temperature had a biphasic pattern in 70% at baseline, 50% in 2nd menstruation cycle, and 61% in 5th menstruation cycle and at least half of the patients may have had ovulation during the treatment. The incidence of adverse drug reactions was 31.8%, with the most common adverse event being metrorrhagia (uterine bleeding occurring inconsistently).

Conclusion:

Dydrogesterone is safe, efficacious, and clinically beneficial in patients with dysmenorrhea, hence indicating that dydrogesterone can be regarded as a treatment option for patients with dysmenorrhea.

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