

Estetrol/drospirenone: Adis Evaluation

Clinical Considerations

- Combined oral contraceptive with estetrol, a natural foetal oestrogen, and drospirenone, a progestin
- Estetrol has lower oestrogenicity than estradiol; thus estetrol may potentially reduce thrombotic risk
- Effective contraceptive with predictable bleeding cycles in a majority of women
- Generally well-tolerated with metrorrhagia being the most common treatment-related adverse event

Plain Language Summary

Background and rationale

- In 2019, an estimated 44% of women aged 15–49 years worldwide used modern contraception methods, and in these women using modern methods, 18% used an oral contraceptive.
- Estetrol/drospirenone is a combined oral contraceptive (COC) which uses estetrol, a plant-synthesised oestrogen naturally produced by the human foetal liver during pregnancy, in combination with drospirenone, a well-known progestin.
- Combined, these hormones suppress ovulation, which constitutes their primary mode of action in preventing pregnancy.
- As estetrol has weaker oestrogen-related effects, it may potentially reduce the risk for blood clots.

Clinical findings

- Estetrol/drospirenone was an effective contraceptive in clinical trials, and most women had regular and predictable bleeding cycles.
- Metrorrhagia (i.e. abnormal bleeding) was the most commonly reported treatment-related adverse effect; however, this is a common issue with hormonal contraceptives.
- Cases of severe migraine headaches, deep vein thrombosis, high potassium levels or depression were rarely reported during clinical trials.

Conclusion

Estetrol/drospirenone is an effective oral contraceptive, which may offer a contraceptive option with a lower risk for blood clots. However, further research is required to confirm the reduced risk of clotting.

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