

Evaluation of the efficacy and safety of a contraceptive containing ethinylestradiol in combination with chlormadinone acetate

Kazan Federal University, 420008, Kremlevskaya 18, Kazan, Russia

Abstract

© Bionika Media Ltd. Objective. To evaluate the efficacy and safety of an agent containing ethinylestradiol (EE) in combination with chlormadinone acetate (CMA) in contraceptive-needing patients within the framework of the pharmacological epidemiological observational project. Subjects and methods. The study enrolled 161 female patients needing contraception. All patients had no contraindications to combined oral contraceptives (COCs) and conditions in which COCs should be used with caution. All the women took EE in combination with CMA in a 21/7 cyclic regimen for contraception. To evaluate its efficacy and safety, the occurrence of pregnancy was assessed within 6 months of EE/CMA intake. To estimate safety parameters, the changes in body weight, blood pressure, and hemostatic parameters that characterized the risk of hypercoagulation disorders were assessed. Results. During the follow-up, no pregnancy occurred in the patients included in the study. Significant changes in weight gain, blood pressure, and improvement in the blood coagulation potential were not observed. The hormonal contraceptive with CMA demonstrated an additional positive effect on the women's emotional state. Conclusion. The findings may conclude that EE in combination with CMA is highly effective and safe and may also highlight its additional positive effects.

<http://dx.doi.org/10.18565/aig.2018.1.83-90>

Keywords

Chlormadinone acetate, Contraception, Efficacy, Ethinylestradiol, Safety

References

- [1] Healthcare in Russia. 2015: Stat.sb./Rosstat. Moscow; 2015. 174. (in Russian)
- [2] Tokova Z.Z., Prilepskaya V.N., Gata A.S., Kuzemin A.A. Statistics of modern methods of contraception in the federal districts of Russia. *Ginekologiya*. 2016; 18(4): 68-71. (in Russian).
- [3] De Irala J., Osorio A., Carlos S., Lopez-del Burgo C. Choice of birth control methods among European women and the role of partners and providers. *Contraception*. 2011; 84(6): 558-64.
- [4] Greben N.F. Psychological tests for professionals. Minsk: Modern school; 2007. 496p. (in Russian)
- [5] Uras R., Orrù M., Pani F., Marotto M.F., Pilloni M., Guerriero S. et al. Endocrinological, metabolic and clinical features of treatment with oral contraceptive formulation containing ethinylestradiol plus chlormadinone acetate in nonobese women with polycystic ovary syndrome. *Contraception*. 2010; 82(2): 131-8.
- [6] Medical eligibility criteria for contraceptive use. 5th ed. Geneva: World Health Organization; 2015.
- [7] Speroff L., Darney P. A clinical guide for contraception. 4th ed. Lippincott Williams & Wilkins; 2005: 64-5.

- [8] Dinger J.C., Heinemann L.A., Kühl-Habich D. The safety of a drospirenone-containing oral contraceptive: final results from the European Active Surveillance Study on oral contraceptives based on 142,475 women-years of observation. *Contraception*. 2007; 75(5): 344-54.
- [9] Schramm G.A., Steffens D. A 12-month evaluation of the CMA-containing oral contraceptive Belara: efficacy, tolerability and anti-androgenic properties. *Contraception*. 2003; 67(4): 305-12.
- [10] Huber J.C., Heskamp M.L., Schramm G.A. Effect of an oral contraceptive with chlormadinone acetate on depressive mood: analysis of data from four observational studies. *Clin. Drug Investig.* 2008; 28(12): 783-91.