Efficacy of a combined oral contraceptive containing 0.030 mg ethinylestradiol/2 mg dienogest for the treatment of papulopustular acne in comparison with placebo and 0.035 mg ethinylestradiol/2 mg cyproterone acetate, Palombo-Kinne E, Schellnhuber I, Gräser T. Contraception 2009; 79: 282–289

A recent Cochrane Review found that combined oral contraceptives (COCs) reduced acne lesion counts, severity grades and self-assessed acne compared to placebo. However, differences in the comparative effectiveness of COCs with varying progesterin types and dosages were less clear. Ethinylestradiol (EE) and cyproterone acetate (CPA) is used as a hormonal treatment for acne, due to its anti-androgenic action. The British National Formulary (BNF) states that it can be a useful treatment option for women who also require oral contraception.

The authors of this study report on a drug company-funded, randomised, double-blind, three-arm study that recruited healthy women aged 16–45 years with mild to moderate facial acne from 65 centres in eastern Europe and the Russian Federation. Their aim was to determine whether a COC-containing dienogest (DNG) was more effective and non-inferior to EE/CPA in the treatment of mild to moderate acne.

Participants were allocated to six cycles of treatment: EE/2 mg CPA (n = 530), 0.035 mg EE/2 mg CPA (n = 541) or placebo (n = 267). Primary outcome measures were the percentage change of inflammatory and total lesion counts, and the percentage of patients with improvements according to the Investigator Global Assessment.

The authors state that all primary analyses provided evidence that EE/DNG was superior to placebo and non-inferior to EE/CPA (p < 0.05). For total lesion count the percentage change (± SD) from baseline to cycle six was: −54.7 ± 26.3% (n = 515) for EE/DNG, −53.6 ± 27.5% (n = 528) for EE/CPA and −39.4 ± 33.6% (n = 259) for placebo.

Points to note include the fact that this study was concerned with treatment of mild to moderate acne, whereas the BNF states that EE/CPA is licensed for women with severe acne not responding to oral anti-bacterial treatment. In addition, the need for treatment was not used. Although a statistically significant (p < 0.05) difference was found between the means of all three primary outcome measures of the four treatment arms, EE/DNG, given the large placebo effect it is unclear whether this equates with a clinically significant difference.

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Reference


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