Acne vulgaris. Tratamento com etinil estradiol e ciproterona

Efficacy of an oral contraceptive containing EE 0.03 mg and CMA 2 mg (Belara) in moderate acne resolution: a randomized, double-blind, placebo-controlled Phase III trial

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BACKGROUND: The study was conducted to assess the effects of the monophasic combined oral contraceptive containing ethinyl estradiol (EE) 0.03 mg and chlormadinone acetate (CMA) 2 mg (EE/CMA) on papulopustular acne of the face, décolleté (low neck) and back; on moderate comedonal acne of the face; and on seborrhea, alopecia and hirsutism. STUDY DESIGN: Three hundred seventy-seven women were randomized (2:1) to receive EE/CMA (n=251) or placebo (n=126) for six medication cycles. Due to the placebo-controlled, double-blind design of the trial, condoms were supplied for contraception. The primary efficacy end point was defined as a reduction of at least 50% in the number of papules and/or pustules of the face from admission to Medication Cycle 6. RESULTS: In total, 64.1% (161/251) of subjects treated with EE/CMA responded compared with 43.7% (55/126) of those taking placebo (p=.0001). The median reduction in papules/pustules on the face at Cycle 6 compared with admission was 63.6% (EE/CMA) compared with 45.3% (placebo group). For comedonal lesions of the face, the reduction in lesion numbers was 54.8% (EE/CMA) compared with 32.4% (placebo). Moderate papulopustular acne of the décolleté decreased by 92.9% (EE/CMA) vs. 50% (placebo group) and of the back by 86.0% and 58.3%, respectively. For these skin conditions, the p values for the relative difference between groups vs. baseline were <.05 at Cycles 3 and 6, in favor of EE/CMA. As part of a self-assessment rating, at least 70.5% (EE/CMA) vs. 41.3% (placebo) reported an at least satisfactory improvement of their moderate acne. Even 39.8% of women taking EE/CMA reported an "excellent improvement" or "complete resolution" of moderate acne compared with 12.7% taking placebo. CONCLUSION: In addition to its contraceptive efficacy described elsewhere, EE/CMA is an effective treatment for moderate papulopustular acne and other androgen-related skin disorders.

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