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Evaluation of the efficacy and safety of hyaluronic acid vaginal gel to ease vaginal dryness: a multicenter, randomized, controlled, open-label, parallel-group, clinical trial.

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Abstract

INTRODUCTION: Atrophic vaginitis is a common occurrence, particularly among postmenopausal women; however, few seek or receive treatment. One therapeutic solution is topically applied products. Estrogen-based treatments have been shown to be effective; however, many patients are reluctant to use such formulations due to health concerns, hence the need to assess the efficacy of acceptable alternatives.

AIM: This multicenter, randomized, controlled, open-label, parallel-group clinical trial set out to evaluate the efficacy and safety of hyaluronic acid vaginal gel to treat vaginal dryness compared with estriol cream in postmenopausal women.

METHODS: One hundred forty-four subjects were randomized, 72 to the test group treated with hyaluronic acid vaginal gel (Hyalofemme) and 72 to the control group treated with estriol cream (Ovestin). Treatment in both groups was applied by means of a device once every 3 days for a total of 10 applications over 30 days.

MAIN OUTCOME MEASURES: Efficacy was measured by grading vaginal dryness and three other vaginal symptoms on a visual analog scale. Safety assessments included vital signs, laboratory examinations of the vaginal microecosystem, vaginal pH value, vaginal B ultrasound, and incidence of adverse events. Assessments were performed at baseline, by telephone after the third application, and at the final visit.

RESULTS: Both hyaluronic acid vaginal gel and estriol cream can significantly improve the clinical symptoms of vaginal dryness in postmenopausal women, with improvement rate of 84.44% and 89.42%, respectively, after 10 applications, without statistically significant difference between them.

CONCLUSION: Both hyaluronic acid vaginal gel and estriol cream are effective in the treatment of vaginal dryness. Hyaluronic acid vaginal gel may be considered as a valid alternative to estrogen-based treatments in relieving the symptoms of vaginal dryness.

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