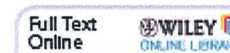


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Cortexolone 17 α -propionate 1% cream, a new potent anti-androgen for topical treatment of acne vulgaris. A pilot randomized, double-blind comparative study versus placebo and tretinoin (Retin-A(®) 0.05% cream).

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Abstract

Background: Acne vulgaris is a disorder of the pilo-sebaceous unit in which the androgens contribute to its onset and persistence. The use of anti-androgens is therefore potentially effective, however anti-androgens for topical use are not available in the market. Cortexolone 17 α -propionate (CB-03-01) is a new potent topical anti-androgen potentially useful in acne vulgaris. **Objectives:** To evaluate the safety and the topical efficacy of cortexolone 17 α -propionate 1% cream in acne vulgaris as compared to placebo and to tretinoin (Retin-A(®) 0.05% cream). **Patients/Methods:** Seventy-seven adult males with facial acne scored 2-3 according to Investigator's Global Assessment (IGA), were randomly subdivided to receive placebo cream (n=15), or CB-03-01 1% cream (n=30), or Retin-A(®) 0.05% cream (n=32) once a day at bed-time for 8 weeks. Clinical efficacy was evaluated every 2 weeks including total lesion count (TLC), inflammatory lesion count (ILC), acne severity index (ASI) and IGA. Safety assessment included local irritancy score (IS), laboratory tests, physical examination, vital signs and recording of adverse events. **Results:** CB-03-01 1% cream resulted very well tolerated, significantly better than placebo on TLC (P = 0.0017), ILC (P = 0.0134) and ASI (P = 0.0090), and also clinically more effective than comparator. The product induced also a faster attainment of 50% of improvement in all above parameters. **Conclusions:** This pilot study supports the rationale for the use of topical anti-androgens in the treatment of acne vulgaris. CB-03-01 1% cream seems to fit with the profile of an ideal anti-androgen for topical use.

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