Efficacy and local tolerability of different spray products in the treatment of mild to moderate acne of the back and chest.

A controlled, 3-arm, assessor-blinded prospective trial.

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Introduction

A new spray formulation containing 0.15% of two vitamin A derivatives (retinol and hydroxypinacolone retinoate) carried in a patented glycospheres system, an antimicrobial peptide (Biopep-15), salicylic acid 0.5% and vitamin E (BR) has been recently developed (Difa Cooper, IFC Group, Caronno Pertusella, Italy). The glycospheres system is an innovative technology which can acts as a penetration enhancer allowing a slow release of the active principles, improving the chemical stability and at the same time the bioavailability . This composition and formulation, from a theoretical point of view, suggests that this product could be particular effective in the treatment of acne involving chest and back. So far no controlled and comparative data are available evaluating the efficacy and tolerability profile of this product.

Study Aim

We evaluated and compared the clinical efficacy of BR with two commonly used sprays for truncal acne treatment, one containing triethylcitrate and ethylinoleate, GT-peptide-10, salycilic acid 0,5% and Zinc Lattate. (AK) (Synchroline Spa, S.Felice del Benaco (BS) and one containing betaine, glycine and salicylic acid 2% (SP) (Canova Skin Care, Milan, Italy).

Study Design

The present study was a balanced, randomized, 3-arm, parallel-groups, and observer-masked prospective 6-week trial. The trial registration number was ISRCTN38383374.

Subjects and Methods

We enrolled a total of 75 subjects (38 men and 37 women, mean age 21 years) after their written informed consent. Main entry criterium was the presence of mild to moderate acne involving back and chest regions (the so called truncal acne). Main Exclusion criteria were: severe forms of acne requiring systemic treatments; other severe skin conditions; use of topical acne medications such as tretinoin, benzoyl peroxide or topical antibiotics within 2 weeks prior the enrollment in the trial; use of oral antibiotics within 30 days; use of systemic corticosteroids within 4 weeks and a Body Mass Index >30. A total of 25 subjects were randomly assigned to each treatment group (BR, AK and SP) with a 1:1:1 ratio.

Study Outcomes

The primary outcome of the study was the evolution of Global Acne Grading System (GAGS) score according to Doshi et al. in comparison with baseline and within groups at week 6. Secondary outcome was the evaluation of skin irritation. In particular safety and tolerability were assessed through evaluations of treated areas tolerability and adverse events. At week 6, the investigator rated erythema (E), burning (b) and xerosis (X), on the basis of a semi-quantitative scale ranging from 0 (none) to 3 (severe). In addition a global skin tolerability score (E+B+X) was also calculated.

Subjects' Characteristics at baseline

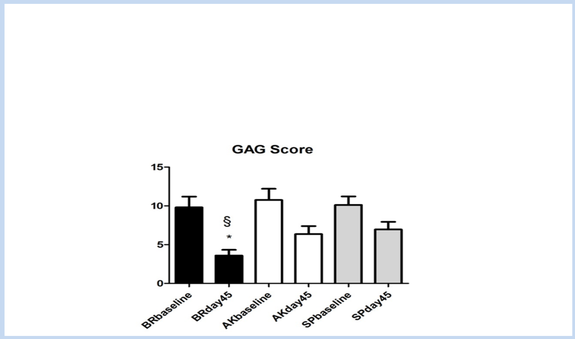
	BR group	AK group	SP group
Number	25	25	25
Men/Women	13/121	4/11	11/14
Age,years, mean (SD)	22(6)	21 (5)	21 (6)
Acne Severity			
Mild, n(%)	21 (84%)	21 (84%)	22 (88%)
Moderate n(%)	4 (16%)	4 (16%)	3 (12%)
GAGS score, mean(SD)	9.8 (6.9)	10.7(7.2)	10.1 (5.5)

Results

At baseline mean±SD of GAG scores were 9.8±7 in BR, 10.7±7.2 in AK and 10.1±5.5 in SP groups, respectively. In comparison with baseline, GAG score was reduced significantly in the BR group (from 9.8 to 3.6; p=0.0001). The reduction in AK and SP in comparison with baseline were also statistically significant (p=0.001). At day 45 GAGS score in BR was statistically significantly lower in comparison with AK (6.3) and SP (6.9) (p=0.03; ANOVA test). A significant greater percentage reduction of GAG scores in comparison with baseline was observed in BR group (-72%; 95% CI from 62% to 83%) in comparison with AK group (-45%; 95%CI from 32% to 57%) (p=0.05) and in comparison with SP group (-36%; 95%CI from 25% to 47%) (p=0.009).

Figure 1

Evolution of GAG scores in the three groups from baseline to day 45 .



BRday45 vs. AKday45 *p=0.03; BRday45 vs.SPday45 §p=0.006; BRday45 vs. BR baseline, AKbaseline vs. AKday45 and SPbaseline vs. SPday45: p=0.0001.

Conclusion

BR spray containing vitamin A derivatives in a glycosphere system, an antimicrobial peptide, salicylic acid and vitamin E has shown to be a more effective treatment of mild to moderate acne of the back and chest in comparison to sprays containing keratolytic and exfoliating agents only. This formulation has also good skin tolerability comparable with anti-acne sprays not containing vitamin A derivatives.