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Efficacy and safety of tretinoin (Microsphere) 0.04% and clindamycin 1% combination gel in comparison to tretinoin 0.025% gel and clindamycin 1% gel in the treatment of moderate to severe acne vulgaris

Shilpi Dhawan
Dr. Reddy's Laboratories, India

Statement of the Problem: Topical retinoids such as tretinoin are currently used as monotherapy and also in combination with clindamycin for treatment of acne. Although the effectiveness of topical tretinoin is well established, the associated skin irritation is a limiting factor in some subjects due to the availability of drug to skin in high concentration in a short period. Novel tretinoin formulation incorporating microsphere technology may improve treatment tolerability, encourage adherence, and contribute to better long-term therapeutic outcomes.

Purpose: The purpose of this study was to evaluate efficacy, safety and tolerability of novel formulation of tretinoin (Microsphere) 0.04% and clindamycin 1% combination gel (T+C) vs. tretinoin 0.025% (T) and clindamycin 1% (C) in the treatment of acne vulgaris.

Methodology & Theoretical Orientation: Eligible male and female subjects ≥12 years with clinical diagnosis of moderate to severe facial acne vulgaris and willing to provide informed consent were randomized in 2:2:1 ratio [Tretinoin (microsphere) 0.04% and clindamycin 1% combination gel (T+C): Tretinoin 0.025% (T): Clindamycin 1%(C)] and instructed to apply a pea-sized amount of the product to the entire face once daily at bedtime for 12 weeks. Efficacy was evaluated by assessing the reduction in count and severity of acne lesions at each visit. Local tolerability assessments were done at all follow-up visits.

Findings: In our study, a statistically significant reduction in acne lesion count was observed with T+C compared to both T and C showing superior efficacy with combination. An early and a higher response rate in efficacy was observed in T+C arm compared to T and C arms. The combination was well tolerated in the study.

Conclusion & Significance: The combination therapy of tretinoin with microsphere technology and clindamycin improved patient satisfaction and adherence to treatment by providing superior efficacy and faster onset of action with better tolerability.

Biography

Shilpi Dhawan has vast experience in conduct of Clinical Research in various therapeutic areas. She completed her MD in Pharmacology and has passion in improving the health and well-being of the patients by bringing innovative ideas for increasing patient compliance, adherence to treatment and safety of the patients. She believes in bringing quality and affordable medicines to the patients by doing quality research. She truly believes in generating the quality data and hence trains the sites in protocol and GCP compliance.

shilpid@drreddys.com

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