



ACNE, ROSACEA, AND RELATED DISORDERS (INCLUDING HIDRADENITIS SUPPURATIVA)

ASSESSING TREATMENT AND RELAPSE IN ROSACEA AFTER CESSATION OF TREATMENT WITH IVERMECTIN 1% CREAM VS METRONIDAZOLE 0.75% CREAM

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Introduction: Ivermectin (IVM) is a broad-spectrum anti-parasitic with anti-inflammatory properties that has been developed as a 1% topical cream for the treatment of the inflammatory lesions of rosacea. Its efficacy and safety has been established in two 12-week phase 3 pivotal trials and 2 long-term (40-week) safety study extensions of the phase 3 studies.

Objective: Compare assess long term efficacy as maintenance therapy: IVM 1% cream QD vs metronidazole 0.75% cream BID.

Methods: This was a two part study ("Part A and B"). "Part A" was an investigator-blinded, randomized, parallel group study. Subjects applied IVM 1% cream QD or metronidazole 0.75% cream BID over 16 weeks. Assessments included inflammatory lesion counts, investigator's global assessment (IGA, 5 point scale), subject's global improvement of rosacea questionnaire (6-point scale), incidence of adverse events (AEs), and tolerability measurements. In "Part B", "Part A" subjects who were considered treatment successes discontinued treatment until their IGA score was >2, at which point they resumed treatment. Efficacy endpoints for "Part B" included time to first relapse, relapse rate, and number of days free of treatment.

Results: Randomized: IVM 1% group, n=478; metronidazole 0.75% cream group, n=484. "Part A" demonstrated that IVM 1% cream was significantly more efficacious after 16 weeks of treatment, with comparable safety, and better tolerability. The median time to relapse significantly favored IVM 1% cream over metronidazole 0.75% cream (P=.0365), and fewer subjects relapsed with IVM 1% cream compared to metronidazole 0.75% cream. The total number of days free of treatment also significantly favored IVM 1% cream (P = .026). IVM 1% cream was safe with 2 subjects reporting 3 related adverse events during the extension.





Conclusion: This study demonstrated the superiority of IVM 1% cream over metronidazole 0.75% cream in treating the inflammatory lesions of rosacea and reducing the likelihood of relapse.

