

Abstract

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The Nicamide Improvement in Clinical Outcomes Study (NICOS): results of an 8-week trial.

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OBJECTIVE: The Nicamide Improvement in Clinical Outcomes Study (NICOS) was an open-label, multicenter, prospective cohort study designed to assess the clinical utility of oral pharmacologic doses of nicotinamide and zinc in 198 patients with acne vulgaris and/or rosacea.

METHODS: The study's primary efficacy measures were patient global evaluation and patient evaluation of the percentage of reduction in inflammatory lesions after 4 and 8 weeks of treatment; overall patient satisfaction also was recorded. The study formulation consisted of nicotinamide 750 mg, zinc 25 mg, copper 1.5 mg, and folic acid 500 microg, marketed as Nicamide (Nic/Zn). Nic/Zn was designed to deliver adequate concentrations of nicotinamide and zinc to effectively treat inflammatory cutaneous conditions with a safety profile suitable for long-term administration.

RESULTS: After a relatively short treatment period of 4 weeks, the number of patients enrolled in NICOS who reported improvement was significantly greater ($P < .0001$) than the number who reported either no change in or worsening of their condition. Of the patients studied, 79% reported their improvement in appearance as moderately better or much better, as measured by patient global evaluation, and 55% reported moderate (26%-50% reduction in lesions) or substantial (>50% reduction in lesions) improvement after 4 weeks of treatment ($P < .0001$). The percentage of patients who responded to therapy continued to increase through the 8 weeks of treatment. When comparing patients who received concomitant oral antibiotic therapy (51/198, 26%) with those who received Nic/Zn tablets as their only oral therapy (147/198, 74%), the percentage of patients who responded to treatment was not significantly different between treatment groups ($P = .13$). This finding was particularly interesting given that most patients studied considered their condition to be of at least moderate severity (143/198, 72%).

CONCLUSION: It appears that the addition of an oral antibiotic to a treatment regimen that includes Nic/Zn tablets may not be necessary because the combination did not significantly increase the percentage of patients responding. Nic/Zn tablets appear to be an effective oral therapy for the treatment of acne vulgaris and rosacea when used alone or with other topical therapies and should be considered a useful alternative approach to oral antibiotics for the treatment of acne vulgaris and rosacea.

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