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Effect of Cephalexin Plus Trimethoprim-Sulfamethoxazole vs Cephalexin Alone on Clinical Cure of Uncomplicated Cellulitis

A Randomized Clinical Trial

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Key Points

Question Does cephalexin plus trimethoprim-sulfamethoxazole yield higher clinical cure rates than cephalexin alone for treatment of patients with uncomplicated cellulitis?

Findings In this randomized clinical trial of 500 patients with cellulitis, the clinical cure rate was not significantly different between those treated with cephalexin plus trimethoprim-sulfamethoxazole vs cephalexin plus placebo (83.5% vs 85.5% in the per-protocol analysis and 76.2% vs 69.0% in the modified intention-to-treat analysis). However, the 95% confidence interval for the difference in the intention-to-treat analysis was -1.0% to +15.5%, which included the minimal clinically important difference of 10%.

Meaning Addition of trimethoprim-sulfamethoxazole to cephalexin did not result in a statistically significant improvement in clinical cure for uncomplicated cellulitis. However, because the imprecision around the findings in the modified intention-to-treat analysis included a clinically important difference favoring the combination, further research may be needed.

Abstract

Importance Emergency department visits for skin infections in the United States have increased with the emergence of methicillin-resistant *Staphylococcus aureus* (MRSA). For cellulitis without purulent drainage, β -hemolytic streptococci are presumed to be the predominant pathogens. It is unknown if antimicrobial regimens possessing in vitro MRSA activity provide improved outcomes compared with treatments lacking MRSA activity.

Objective To determine whether cephalexin plus trimethoprim-sulfamethoxazole yields a higher clinical cure rate of uncomplicated cellulitis than cephalexin alone.

Design, Setting, and Participants Multicenter, double-blind, randomized superiority trial in 5 US emergency departments among outpatients older than 12 years with cellulitis and no wound, purulent drainage, or abscess enrolled from April 2009 through June 2012. All participants had soft tissue ultrasound performed at the time of enrollment to exclude abscess. Final follow-up was August 2012.

Interventions Cephalexin, 500 mg 4 times daily, plus trimethoprim-sulfamethoxazole, 320 mg/1600 mg twice daily, for 7 days (n = 248 participants) or cephalexin plus placebo for 7 days (n = 248 participants).

Main Outcomes and Measures The primary outcome determined a priori in the per-protocol group was clinical cure, defined as absence of these clinical failure criteria at follow-up visits: fever; increase in erythema (>25%), swelling, or tenderness (days 3-4); no decrease in erythema, swelling, or tenderness (days 8-10); and more than minimal erythema, swelling, or tenderness (days 14-21). A clinically significant difference was defined as greater than 10%.

Results Among 500 randomized participants, 496 (99%) were included in the modified intention-to-treat analysis and 411 (82.2%) in the per-protocol analysis (median age, 40 years [range, 15-78 years]; 58.4% male; 10.9% had diabetes). Median length and width of erythema were 13.0 cm and 10.0 cm. In the per-protocol population, clinical cure occurred in 182 (83.5%) of 218 participants in the cephalexin plus trimethoprim-sulfamethoxazole group vs 165 (85.5%) of 193 in the cephalexin group (difference, -2.0%; 95% CI, -9.7% to 5.7%; $P = .50$). In the modified intention-to-treat population, clinical cure occurred in 189 (76.2%) of 248 participants in the cephalexin plus trimethoprim-sulfamethoxazole group vs 171 (69.0%) of 248 in the cephalexin group (difference, 7.3%; 95% CI, -1.0% to 15.5%; $P = .07$). Between-group adverse event rates and secondary outcomes through 7 to 9 weeks, including overnight hospitalization, recurrent skin infections, and similar infection in household contacts, did not differ significantly.

Conclusions and Relevance Among patients with uncomplicated cellulitis, the use of cephalexin plus trimethoprim-sulfamethoxazole compared to cephalexin alone did not result in higher rates of clinical resolution of cellulitis in the per-protocol analysis. However, because imprecision around the findings in the modified intention-to-treat analysis included a clinically important difference favoring cephalexin plus trimethoprim-sulfamethoxazole, further research may be needed.

Trial Registration clinicaltrials.gov Identifier: [NCT00729937](https://clinicaltrials.gov/ct2/show/study/NCT00729937)



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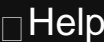
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