Echinacea for the Prevention of Upper Respiratory Tract Infections

Melchart D, Walther E, Linde K, Brandmaier R, Lersch C. Echinacea root extracts for the prevention of upper respiratory tract infections. Arch Fam Med 1998; 7:541-5

Clinical question **Do extracts of *Echinacea pupurea* or *Echinacea augustifolia* prevent the development of upper respiratory tract infections (URIs)?**

Background Echinacea, the top selling herbal product in the United States for the past 4 years, is widely used in the United States and Europe for the treatment of URIs. Few adverse effects of echinacea preparations have been reported. Despite the widespread use of echinacea products for the prevention and treatment of URIs, their efficacy is controversial. Clinical studies to support their use in the treatment of URIs are primarily published in German, use many different doses and formulations, and frequently involve multiple herbal products in combination with echinacea.[1] The authors of this trial attempted to determine if the immunomodulatory effects of echinacea would provide benefit in the prevention of URIs.

Population studied Volunteers aged 18 to 65 years (n = 289) who were "free of acute illness" were recruited from 4 military sites and one industrial plant in Munich, Germany, over 2 winter seasons. Volunteers were excluded if they had experienced acute URI or other infections in the 7 previous days; had a serious progressive disease; required steroid, antibiotic, or immunosuppressive therapy; had a history of allergy to the *Compositae* family; or were pregnant. Nearly half of each group had previously taken an echinacea product.

Study design and validity This was a randomized double-blind placebo-controlled trial of 50 drops of ethanolic root extracts (plant extract ratio 1:11 in 30% alcohol) of *E pupurea*, *E augustifolia*, or placebo (colored ethanolic solution) given twice daily for 5 days each week for 12 weeks. Patients were evaluated at baseline, 4, 8, and 12 weeks, with instructions to contact a study physician in the event of any symptoms of a URI. Study physicians evaluated patients on the basis of a standardized form and subjectively classified the severity of infection. Patients were given a symptom diary when they reported to a study physician for evaluation of URI. No other symptom or adverse event diaries were kept. Data were analyzed on an intention-to-treat basis. A major concern is that subjects did not report concurrent use of echinacea in other forms, or any use of other pharmacologic agents (allopathic and complementary) that may potentially impact URI incidence or severity. A further concern noted by the authors is the near impossibility of blinding for the echinacea extracts because of their characteristic taste.

Outcomes measured The primary outcome measure was time to first URI. Secondary outcome measures included adverse effects, "global assessment" (by the participants), and the number of volunteers with at least one URI.

Results Forty-five patients dropped out of the study (15 patients in each group) because of adverse effects, lack of efficacy, and "other reasons." There were no significant differences between the 3 groups in mean days to first URI, the percentage of patients with one or more infections, and number of participants reporting adverse effects. The relative risk of development of at least one URI was .87 (95% CI, .59-1.30) in the *E augustifolia* group and .80 (95% CI, .53-1.31) in the *E pupurea* group compared with placebo. The only significant result was that more patients in the 2 echinacea groups believed they had received benefit from their treatment ($P = .04$), possibly because of the lack of blinding of the echinacea extracts.

Recommendations for clinical practice **The specific ethanolic extracts of echinacea used in this trial, while without significant toxicity, do not appear to have a clinically or statistically significant effect on the prevention of URIs. While this study does not support the effectiveness of echinacea in the prevention of URIs, it also does not address the efficacy of echinacea in the treatment of URI symptoms. Further evaluations of echinacea should be conducted, using standardized, readily available formulations, and with sufficient numbers of patients to detect clinically and statistically significant effects of echinacea in the prevention and treatment of URIs.**

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REFERENCE

1. Melchart D, Linde K, Worku F, Bauer R, Wagner H. Immunomodulation with Echinacea - a systematic review of controlled clinical trials. Phytomedicine 1994; 1:245-54.

Low-Dose Omeprazole for Erosive Esophagitis

Bardhan KD, Cherian P, Vaishnavi A, et al. Erosive esophagitis: outcome of repeated long term maintenance treatment with low dose omeprazole 10 mg or placebo. Gut 1998; 43: 458-64.

Clinical question **In patients with endoscopically diagnosed erosive esophagitis, is low-dose omepra-**