Infections in Children: A Randomized Treatments of the Common Cold: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial


Purpose of the study. Echinacea purpurea stimulates the immune response and is promoted to reduce symptom severity and the duration of upper respiratory tract infections. The researchers sought to determine the efficacy of a standardized preparation of *E. purpurea* in reducing symptom severity and duration of the common cold.

Study Population and Methods. A randomized, double-blind, placebo-controlled design was used. Patients received either 100 mg of *E. purpurea* (freeze-dried pressed juice from the aerial portion of the plant) or a lactose placebo 3 times daily until cold symptoms were relieved or until the end of 14 days, whichever came first. Symptoms (sneezing, nasal discharge, nasal congestion, headache, sore or scratchy throat, hoarseness, muscle aches, and cough) were scored subjectively by the patient and recorded daily in a diary. Kaplan-Meier curves were used to estimate the survival function of time to resolution in each group. The Wilcoxon rank-sum test was used to compare time to resolution between the 2 groups.

Results. One hundred twenty-eight patients were enrolled within 24 hours of cold-symptom onset. Group demographic distribution was comparable for gender, age, time from symptom onset to enrollment in the study, average number of colds per year, and smoking history. No statistically significant difference was observed between treatment groups for either total symptom scores (P = .29–.90) or mean individual symptom scores (P = .09–.93). The time to resolution of symptoms was not statistically different (P = .73).

Conclusions. The preparation of *E. purpurea* at these doses was not effective in relieving the severity or duration of the common cold.

Reviewer’s Comments. It is probably not a surprise that inconsistent results have been found in different studies, because there is no required standardization for potency or content of echinacea. We can thank the US Congress, who in the mid-1990s capitulated to the food-supplements industry and removed Food and Drug Administration regulation of echinacea and other similar products. Although we generally think of echinacea as fairly harmless, it can reduce the effectiveness of corticosteroids, which would be commonly used in viral-induced asthma. It also can cause hypersensitivity reactions to persons allergic to ragweed.

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Efficacy and Safety of Echinacea in Treating Upper Respiratory Tract Infections in Children: A Randomized Controlled Trial


Purpose of the Study. To determine if echinacea is effective in reducing the duration and/or severity of upper respiratory infection (URI) symptoms in children and assess its safety in this age group.

Study Population. Five hundred twenty-four healthy children, aged 2 to 11 years, were enrolled from a practice-based pediatric research network and an alternative-medicine institution in the Seattle, Washington, area. Each child was enrolled in the project for a 4-month period in 2 consecutive years during the peak rhinovirus season. Data were collected on up to 3 URIs per study patient. Twenty-three percent of the children in the active-treatment group were in a day care setting versus 13% in a placebo group.

Methods. This was a randomized, double-blind, placebo-controlled trial of echinacea for up to 3 URIs over the 4-month study period. Study medication was begun at the onset of symptoms and continued throughout the URI for a maximum of 10 days. Primary outcomes were duration and severity of symptoms and adverse events recorded by parents.

Results. Data were analyzed on 707 URIs that occurred in 407 study patients. Median duration of URIs was 9 days. There was no difference in duration between URIs treated with echinacea or placebo (P = .89). There was also no difference in the overall severity of URI symptoms between the 2 treatment groups (P = .69). There were no statistically significant differences between the 2 groups for peak severity of symptoms, number of days of peak symptoms, number of days of fever, or parental global assessment of severity of the URI. There was no difference in the rate of adverse events reported in the 2 treatment groups; however, rash occurred during 7.1% of the URIs treated with echinacea and 2.7% of URIs treated with placebo (P = .008).

Conclusions. Echinacea as used in this study was not effective in decreasing duration or severity of URI symptoms in healthy children 2 to 11 years old. Its use was associated with an increased risk of rash.

Reviewer’s Comments. Echinacea, derived from wildflowers from the daisy family (family Compositae), is one of the most commonly used herbal preparations in the United States, with reported sales of more than $300 million annually despite limited evidence of clinically beneficial effects in the treatment of viral respiratory infections.

This study is one of the largest randomized, controlled trials of echinacea treatment in patients of any age. In addition to the large sample size, the validity of the results is strengthened because enrolled patients had sought care from both traditional and alternative providers in an attempt to negate the effects of preconceived biases about echinacea. These data provide additional information regarding lack of efficacy of echinacea in treating the 6 to 8 colds an average child has each year.

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Efficacy and Safety of Echinacea in Treating Upper Respiratory Tract Infections in Children: A Randomized Controlled Trial

Alan Goldsobel

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