Swiss Echinacea Extract Shown Safe and Effective in Preventing Colds in Largest Echinacea Clinical Trial

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By Amy C. Keller (/resources/herbalgram/authors/keller-amy-c/)

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Colds and flu, associated with a variety of viral infections, are characterized by symptoms such as sore throat, cough, and nose irritations, as well as systemic complaints such as headache, malaise, and fever. The common cold alone causes great discomfort and is a major reason for school and work absences, as well as physicians visits.1 Preventative strategies have included antiviral agents or vaccines targeted towards infection prevention or inhibition of viral replication; however, common problems arise with adverse side effects (ASE) and/or the failure to protect certain populations.

Echinacea (*Echinacea purpurea*, Asteraceae) is used widely as an immune system modulator as well as in common cold prevention strategies.2 Many clinical studies investigating the use of echinacea in cold prevention have shown conflicting results or have had too small a sample size to detect significant effects. However, significant preventive effects were observed when 3 trials on standardized echinacea extracts were combined in a meta-analysis.3 (These studies were conducted by Bioforce AG in cooperation with Sebastian Johnston, MD, PhD, from the Imperial College in London.) Finally, tolerability and safety are critical considerations for therapies designed for long-term, preventive use. The most recent randomized, double-blind, placebo-controlled trial investigated the safety profile and efficacy of the long-term usage of a proprietary echinacea formulation for prevention of colds and flu.

This study took place at the Common Cold Center at Cardiff University in Cardiff, Wales. Healthy subjects were randomized to either echinacea or placebo for 4 months. At the initial clinical visit, subjects received study medication for 1 month in addition to a diary for documenting ASEs, incidences of colds and associated symptoms, and medication use other than given treatments. Subjects brought unused treatments and completed diaries to monthly clinical visits and also were given kits to take nasal swabs for viral identification.

An alcoholic extract of fresh echinacea extract was used in this trial (Echinaforce®, made from E. purpurea, 95% aerial parts and 5% roots, prepared by Bioforce AG; Roggwil, Switzerland). Material was standardized to 5 mg/100 g of dodecatetraenoic acid isobutylamide and tested negative for endotoxin. Placebo was comparable in appearance, smell, and taste, with the same percentage of alcohol and identical packaging. Total dosage was based on Bioforce AG's

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instructions and consisted of 0.9 ml of extract or placebo 3 times per day in water; this material was held in the mouth for 10 seconds (2,400 mg of extract daily) in order to achieve maximal local antiviral and anti-inflammatory effects at the pharynx. If subjects had a cold, they were asked to increase dosage to 0.9 ml 5 times per day (4,000 mg of extract). Leftover bottles were weighed for remnant of extract, and diaries were consulted to assess compliance.

Subjects were recruited on campus, at least 18 years old, and in good health with a recent history of 2 or more colds per year. Those pregnant, who had a chance of becoming pregnant, who were breastfeeding, who had a cold at the time of recruitment, who were on either antiviral or antibacterial medication, who abused drugs or alcohol, or who suffered from psychological diseases or epilepsy were excluded. Exclusion criteria also did not permit subjects with the following: a history of suicide attempts, upcoming surgery, chronic or autoimmune diseases, and asthma or allergies, particularly to members of the Asteraceae plant family. A preliminary study showed blinding to be efficient as approximately half the subjects in both the echinacea and placebo groups guessed that they had the echinacea treatment. Additionally, a power calculation based on a beneficial effect of 25% with the echinacea treatment and a protocol deviation and drop-out rate of 20% yielded an ideal sample size of 750 participants for the efficacy variable (number of days with colds).

Blood samples were taken from subjects for screening of blood cell counts and hematological and other measurements. Both subjects and physicians were asked to rate echinacea tolerability. Descriptions for ASEs as related to the treatments ranged from “not related” to “certain.” Those ASEs that were “possibly” associated with treatment were considered adverse drug reactions (ADRs). Parameters for colds included the amount of colds, the total number of days with colds, and colds that required addition medication. Characterization of viral infections was also conducted.

Out of 755 subjects included and randomized, 82 subjects dropped out, leaving 673 who finished the study regularly. Reasons for subject dropout included loss of contact (there was no contact post randomization; n=38), withdrawal of consent (n=16), “technical reasons” (n=3), health or ASE problems (n=3), and unknown reasons (n=22). There were no baseline differences between groups with the exception of cold susceptibility; subjects randomized to the echinacea group were, by chance, significantly more susceptible to colds than those in the placebo group ($P<0.05$). This was expected to bias the efficacy results against the echinacea group.

ADRs were reported by 9.0% of the echinacea group and 10.0% of the placebo group; the echinacea treatment was identified to be non-inferior to placebo treatment in regard to the rate of occurrence, as even fewer ADRs were observed. In the echinacea group, 177 subjects documented 293 ASEs, and 172 subjects in the placebo group mentioned 306 ASEs. Also, in the echinacea group, 4 ASEs resulted in discontinuation of treatment, while 3 ASEs caused discontinuation in the placebo group. One severe ASE was reported in the placebo group while none were reported from the echinacea group. No significant differences were detected in the amount of ASEs between groups. Also, no significant differences were reported in the blood parameters either after echinacea treatment or between groups. Assessment of tolerability by subjects resulted in ratings of “good” or “very good” in 64% of the echinacea group and 71% of the placebo group.

Those in the echinacea group experienced 149 colds lasting a combined total of 672 days, while subjects in the placebo group reported 188 colds with a length of 850 days. The total number of days with colds was significantly fewer in the echinacea group than the placebo group ($P<0.05$, as measured in the intention-to-treat population). Those in the echinacea group also experienced fewer recurring colds than those in the placebo group (65 vs. 100, respectively; $P<0.05$). In addition, a greater number of subjects with colds in the placebo group used medication such as aspirin, paracetamol (acetaminophen), and ibuprofen as compared with those in the echinacea group (88 vs. 58, respectively; $P<0.05$).

Of the nasal swabs collected (n=201), viral infection was identified in 54 samples from the echinacea group and 74 in the placebo group. Significantly fewer samples from the echinacea group contained influenza, corona-, metapneumo-, respiratory syncytial-, and parainfluenza viruses as compared the placebo group (24 vs. 47, respectively; $P<0.05$). Additionally, in subjects

with 100% protocol compliance, 36 colds with a combined total duration of 155 days were reported from the echinacea group (n=88) as compared with 58 colds in 268 days in the placebo group (n=99, P<0.0001).

In summary, preventive therapies for colds and flu should be both well tolerated and efficacious. The echinacea preparation used here exhibited a very "good" safety profile for long-term usage. This study reports that echinacea long-term prevention was associated with fewer cold episodes, fewer days with colds, and fewer colds that required additional medication, suggesting efficacy against infection. The study mentions that these data may have been confounded by the significant difference of cold susceptibly between groups and less use of pain-relieving pharmaceutical drugs in the echinacea group. If an adjustment for these co-variables had been conducted, an even more beneficial preventive effect for the echinacea formulation probably would have been shown.

This study also characterized viruses. Although the sample size was small, those in the echinacea group had significantly fewer viral infections than those in the placebo group. This may preliminarily indicate clinical antiviral activity as it agrees with the authors' in vitro results on the same proprietary extract (Echinaforce). In conclusion, this study claims to be not only the largest ever conducted on the clinical effects of echinacea, but the first to employ the detection of specific viruses in this manner. The conclusions from this well-powered, robust clinical trial contribute substantially to the case for the use of echinacea preparations, particularly this specific formulation, in common cold prevention.

—Amy C. Keller, PhD

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