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**File: ■ Andrographis (*Andrographis paniculata*)
■ KalmCold™
■ Upper Respiratory Tract Infections**

HC 041051-399

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RE: Andrographis Extract Shown to Provide Relief for Common Cold Symptoms

Saxena RC, Singh R, Kumar P, et al. A randomized double blind placebo controlled clinical evaluation of extract of *Andrographis paniculata* (KalmCold™) in patients with uncomplicated upper respiratory tract infection. *Phytother*. 2010;10:178-185.

Andrographis (*Andrographis paniculata*) is an annual herb native to India and Sri Lanka. It is used to treat the common cold, a viral infection of the upper respiratory tract. The andrographis component andrographolide has anti-inflammatory and immunostimulant mechanisms of actions. The purpose of this study was to evaluate the efficacy of an extract of andrographis called KalmCold™ (M/s Natural Remedies Pvt. Ltd.; Bangalore, India).

Patients (18-60 years old) suffering from 2 or more symptoms of the common cold (cough, expectoration, running nose, headache, fever, sore throat, earache, malaise/fatigue, and sleep disturbance) and who were sick for fewer than 3 days participated in this randomized, double-blind, placebo-controlled study. Those suffering from anything other than the common cold or using medicines that might impact its symptoms were excluded. Participants were recruited from 4 centers in India between May and November 2007. Patients of both genders were randomly assigned to receive placebo (n = 111) or KalmCold (n = 112) 200 mg/day for 5 days, taking a capsule after breakfast and dinner. KalmCold contains 31.30% w/w andrographolide per 100 mg capsule. Patients rated each of the 9 symptoms on a visual analogue scale on days 1, 3, and 5 of treatment.

Three patients in the placebo group were lost to follow-up and excluded from analysis. No KalmCold-treated patients discontinued from the study. At baseline, both treatment groups had similar symptom severity scores. In both treatment groups, the mean symptom scores decreased significantly from day 1 to day 3 ($P < 0.05$) and there was no significant difference between the 2 groups. However, in the placebo group, from day 3 to day 5, no symptoms except expectoration improved significantly. In contrast, in the KalmCold group, from day 3 to day 5, all symptoms improved significantly ($P < 0.05$), except earache. At day 5, 14 of 108 placebo-treated patients reported that their symptoms were aggravated. This is significantly more than the single KalmCold-treated

patient that reported an aggravation of symptoms at day 5 ($P < 0.05$). A total of 17 placebo-treated patients and 2 KalmCold-treated patients had either an increase of overall symptom scores or showed no response to treatment ($P < 0.05$).

Six KalmCold-treated patients had minor adverse events (AEs): vomiting ($n = 1$), epistaxis (nosebleed, $n = 1$), urticaria (itchy rash, $n = 1$), and diarrhea ($n = 3$). Two of the 3 patients with diarrhea also had nausea or lethargy. Three placebo-treated patients had AEs: diarrhea ($n = 1$), vomiting ($n = 1$), and moderate rigor (stiffness, $n = 1$). There was no significant difference between groups in the number of AEs. Except for vomiting and urticaria in the KalmCold-treated patients, all other AEs spontaneously resolved without treatment.

The authors conclude that KalmCold was 52.7% more effective (based on the effect size) than placebo at treating the common cold. The findings are in agreement with other studies of andrographis. One parameter that was not included that would have been an interesting addition would have been “patient satisfaction.” Patient satisfaction questions, such as “Would you use this treatment again?”, are commonly used in clinical trials of pharmaceuticals. It is an additional indicator of whether the patient believes that the treatment provided a benefit. Aside from this point, the study was well-designed and executed.

—Heather S. Oliff, PhD

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