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A randomized double blind placebo controlled clinical evaluation of extract of *Andrographis paniculata* (KalmCold™) in patients with uncomplicated upper respiratory tract infection

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Abstract

A randomized, double blind placebo controlled clinical study was conducted to evaluate the efficacy of KalmCold™, an extract of *Andrographis paniculata*, in patients with uncomplicated upper respiratory tract infection (URTI). The assessment involved quantification of symptom scores by Visual Analogue Scale. Nine self evaluated symptoms of cough, expectoration, nasal discharge, headache, fever, sore throat, earache, malaise/fatigue and sleep disturbance were scored. A total of 223 patients of both sexes were randomized in two groups which received either KalmCold™ (200 mg/day) or placebo in a double blind manner. In both the treatments, mean scores of all symptoms showed a decreasing trend from day 1 to day 3 but from day 3 to day 5 most of the symptoms in placebo treated group either remained unchanged (cough, headache and earache) or got aggravated (sore throat and sleep disturbance) whereas in KalmCold™ treated group all symptoms showed a decreasing trend. Within groups, mean scores of symptoms in both the groups decreased significantly ($p \leq 0.05$) from day 1 to day 3 and day 5 while from day 3 to day 5 all symptoms except expectoration in placebo group did not improve significantly whereas in KalmCold™ treated group all symptoms improved significantly ($p \leq 0.05$) except earache. Comparing mean between both groups, all symptoms at day 1 and day 3 were found to be the same while at day 5 all symptoms except earache in KalmCold™ treated group improved significantly ($p \leq 0.05$) than placebo group. Similarly, within groups, overall scores of all symptoms in both the groups decreased significantly ($p \leq 0.05$) from day 1 to day 3 and day 5 while from day 3 to day 5 placebo group did not improve significantly whereas KalmCold™ treated group showed significant improvement ($p \leq 0.05$). On between groups analysis, KalmCold™ group showed significant reduction ($p \leq 0.05$) in overall symptom scores as compared to placebo group. In both placebo and KalmCold™ treated groups, there were only a few minor adverse effects with no significant difference in occurrence ($Z = 0.63$; $p > 0.05$). The comparison of overall efficacy of KalmCold™ over placebo was found to be significant ($p \leq 0.05$) and it was 2.1 times (52.7%) higher than placebo. The findings of this study revealed that KalmCold™ was effective in reducing symptoms of upper respiratory tract infection.

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Keywords

Andrographis paniculata; KalmCold™; Upper respiratory tract infection; Common cold; Efficacy; Double blind placebo controlled trial