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FILE: ▪Umckaloabo (*Pelagonium sidoides*)
▪EPs® 7630
▪Bronchitis

HC 010261-297

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RE: Special Extract of Traditional African Herb, Umckaloabo, Treats Bronchitis in Clinical Trial

Chuchalin AG, Berman B, Lehmacher W. Treatment of acute bronchitis in adults with a *Pelargonium sidoides* preparation (EPs® 7630): A randomized, double-blind, placebo-controlled trial. *Explore*. 2005;1:437–445.

Acute bronchitis is a common upper respiratory tract infection caused primarily by the respiratory syncytial virus (RSV), but also by the coxsackie, influenza, parainfluenza, and ECHO viruses or adenoviruses. Conventional medical treatment is aimed primarily at reducing symptoms. Treatment with antibiotics does not substantially decrease the duration of the illness; however 70% of the cases of acute bronchitis continue to be treated with antibiotics. This clinical trial evaluated the potential of an herbal medicinal preparation of *Pelargonium sidoides* for the treatment of acute bronchitis. *P. sidoides* is an herb used traditionally in South Africa for its ability to treat various symptoms of upper respiratory tract infections.

This clinical trial was conducted in Russia at 6 urban primary care outpatient clinics. Included in the study were 124 subjects (37 men, 87 women, mean age approximately 36 years) diagnosed with acute bronchitis and a Bronchitis Severity Score (BSS) ≥ 5, and duration of symptoms of ≤ 48 hours. The BSS is a 5-point scale that scores bronchitis symptoms, namely cough, sputum, rales/rhonchi (a crackling sound during respiration related to congestion in the bronchii), chest pain during coughing, and dyspnea (difficult breathing).

Symptoms were assessed through interviews with the subjects, in which a score of 0 = the absence of symptoms, 1 = mild symptoms, 2 = moderate, 3 = severe, and 4 = very severe symptoms. Excluded from the study were people who should be receiving antibiotics (e.g., those with suspected pneumonia), people who had been treated with antibiotics within 4 weeks of the study, people with allergic bronchial asthma, tendency to bleed, hypersensitivity or possible hypersensitivity to the medication, severe heart, renal, liver

disease, and those on other medications that might impair the validity of the study results (e.g., antibiotics).

The primary outcome measure was the change in BSS compared to placebo. The secondary outcomes measures were BSS < 5 at the conclusion of the study, a decrease of BSS ≥ 5 points compared to baseline, consumption of paracetamol (a.k.a. acetaminophen, a non-prescription analgesic), change in individual subjects' symptoms of BSS, and the results of the SF−12 Health Survey and EQ-5D quality of life questionnaires. An additional outcome measure was the Integrative Medicine Outcome Scale (IMOS), which is a 5-point scale that rates whether a subject has achieved "complete recovery," "major improvement," "slight to moderate improvement," "no change," or "deterioration." Subject satisfaction with the treatment was also assessed by using the Integrative Medicine Patient Satisfaction Scale (IMPSS), a 5-point scale with the ratings of "very satisfied," "satisfied," "neutral," "dissatisfied," and "very dissatisfied," Adverse events were recorded to determine their frequency, nature, and severity using a 4-point rating scale.

Subjects in the treatment group were prescribed a proprietary extract of *P. sidoides*, EPs 7630 (Dr. Willmar Schwabe GmbH & Co., Karlsruhe, Germany) 4.5 mL (30 drop) 3 times daily 30 minutes before or after meals for 7 days or matching placebo. (EPs 7630 consists of of an ethanolic extract at a concentration of 1:9-11 of the root of *P. sidoides* as the active constituent and 85% glycerol – 80% ethanolic extract and 20% glycerol.) BSS significantly decreased from 7.2 ± 3.1 points in the treatment group compared to 4.9 ± 2.7 points in the placebo group ($P < 0.0001$). This showed "a highly significant superiority of EPs 7630 compared with placebo on day seven." Clinical superiority of EPs 7630 was detected as early as 3 days, with a mean BSS at that time of 4.4 ± 2.2 for the treatment group compared to 6.2 ± 2.5 points in the placebo group from baseline to day 7 of treatment ($P < 0.0001$).

BSS of less than 5 points was noted in 61 of 64 subjects (95.3%) in the EPs 7630 group compared to 35 of 60 subjects (58.3%) in the placebo group ($P < 0.0001$). Similarly, a decrease in BSS of at least 5 points occurred in 58 of 64 subjects (90.6%) in the EPs 7630 group compared to 31 of 60 subjects (51.7%) in the placebo group from baseline to day 7 of treatment ($P < 0.0001$). These 2 criteria defined "rapid recovery," which was detected in 58 of 64 subjects (90.6%) in the EPs 7630 group compared to 25 of 60 subjects (41.7%) in the placebo group ($P < 0.0001$). Symptomatic improvement of rales/rhonchi, chest pain during coughing, and dyspnea after 7 days of EPs 7630 administration exceeded 90% of that group, whereas less than 60% of the placebo group experienced recovery of these symptoms. Rales/rhonchi were absent in 55 of 60 subjects (91.7%) in the EPs 7630 group vs. 29 of 59 subjects (49.2%) in the placebo group ($P < 0.0001$). Chest pain during coughing was absent in 55 of 58 subjects in the treatment group (94.8%) compared to 29 of 52 subjects (55.8%) in the placebo group ($P < 0.0001$). Cough was the symptom that showed the slowest rate of recovery in both groups. Cough disappeared in 20 of 64 subjects (31.3%) in the treatment group compared to 3 of 60 subjects (5.0%) in the placebo group ($P < 0.0001$). Similarly, hoarseness disappeared in 45 of 58 subjects (77.6%) in the treatment group compared to 20 of 52 subjects (38.5%) in the placebo group ($P < 0.0001$).

At the end of the study period 54 of 64 subjects (84.4%) in the treatment group compared to 18 of 60 subjects (30.0%) of the placebo group were assessed as "major improved or completely recovered" by the IMOS. This assessment was given to 43 of 64 subjects (67.2%) in the treatment group compared to 11 of 60 subjects (18.3%) of the placebo group by days 3–5 of treatment. A noticeable effect of EPs 7630 treatment was described within 2–5 hours by 2 of 64 subjects (3.1%) and within 1–2 days by 14 of 64 subjects (21.9%). The majority of subjects in the treatment group reported remission of their acute bronchitis symptoms by day 7, whereas "many patients" in the placebo group reported experiencing no change by day 7. Adverse events were not significantly different between treatment and placebo groups. No serious adverse events were reported.

This clinical trial agrees with an earlier, larger study showing the superiority of EPs 7630 over placebo for the treatment of acute bronchitis in 468 subjects.[1] A comprehensive review of the traditional uses and modern research on *P. sidoides* was published in 2003[2] and another recent paper reviews the clinical pharmacology of *P. sidoides* special extract.[3] The safety and efficacy of this formula provides an alternative to the ineffective conventional treatments for acute bronchitis.

—John Neustadt, ND

References

[1]Matthys H, Eisebitt R, Seith B, Heger M. Efficacy and safety of an extract of *Pelargonium sidoides* (EPs 7630) in adults with acute bronchitis. A randomised, double-blind, placebo-controlled trial. *Phytomed.* 2003;10 Suppl 4:7-17. [HC 110134.254 http://www.herbalgram.org/herbclip/herbclip.php?a=reviews&a2=43781]

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[3] Brown D. Extract of *Pelargonium sidoides*: South African Herbal Remedy Successfully Treats Acute Bronchitis and Tonsillopharyngitis. *HerbalGram*. 2004;63:17-19. [http://www.herbalgram.org/herbalgram/articleview.asp?a=2703]

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