

Overview of clinical trials with *Pelargonium sidoides* L. in the treatment of ARI

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Pelargonium sidoides DC is a plant originated in South Africa with a long tradition of use in folk medicine. Chemical constituents of *Pelargonium s.* are: coumarins, coumarin glycosides, coumarin sulphates, flavonoids, proanthocyanidins, phenolic acids and phenylpropanoid derivatives (Brendler 2008; Kolodziej 2008). Most of clinical studies have been conducted administering the extract EPS 7630[®] derived from roots of *Pelargonium s.* EPS 7630[®] is employed for the treatment of acute respiratory tract infections (ARIs), where the administration of antibiotics is unnecessary or even dangerous for the possibility to produce side effects without any beneficial action (Ulbricht 2010). Scope of the present review has been collecting, analyzing and commenting clinical and safety data available on *Pelargonium s.* for the treatment of ARI. Even though some reviews about *Pelargonium s.* have been published, the most updated of them was published 3 years ago, despite the fact that new data have been released. Consequently, a complete and independent review on scientific literature on clinical putative efficacy and safety of this plant appears desirable. The methodological accuracy of clinical trials has been evaluated in accordance to current and consolidated guidelines in reporting herbal medicine clinical trials, in order to offer insights about the adequate use of *Pelargonium s.* in clinical practice. Systematic research was conducted independently by two researchers in the databases Medline, Pubmed, Embase, Cochrane Database of Systematic Reviews, Natural Standard, and the Natural Medicines Comprehensive Database. Each database was searched from its respective inception until May 2031. The search terms used were *Pelargonium sidoides*, *Pelargonium radix*, *Pelargonium root*, *Umckaloabo*. Eighteen (N = 18) included clinical trials, published between the 1999 and May 2013, showed generally a good quality methodological standard. They evaluated efficacy and safety of *Pelargonium* extracts in the treatment of various respiratory diseases: acute bronchitis, common cold, asthma attacks during respiratory infections, rhinosinusitis, tonsillopharyngitis, and also immune response linked to secretory IgA (Matthys 2007; Ulbricht 2010). Trials on acute bronchitis in adults have been conducted on 1600 patients, in on 2099 patients (adults and children) in a multicenter study, and on 500 children and adolescents subjects. The efficacy in the treatment of common cold, rhinosinusitis, asthma exacerbation during respiratory infections and tonsillopharyngitis has been also evaluated. Clinical studies concluded that *Pelargonium s.* preparations are effective in relieving symptoms in acute bronchitis in adults and children. Considering the other indication small sample sizes and lack of control in some studies suggest that it is desirable to replicate these trials in order to allow a firm conclusion to be drawn on the use of *P. sidoides* in clinical practice. Mild gastrointestinal disorders, type I acute hypersensitivity reaction have been the most common adverse events registered during the trials. Hepatotoxic action could occur in patient affected by hepatopathy (Teschke 2012). The inappropriate use of antibiotics represents the main cause of rising drug resistance, according to World Health Organization it is currently one of the most important issue in global public health (Angulo 2009). In conclusion data suggest that there is encouraging evidence that *Pelargonium s.* is effective compared to placebo and shows a good safety profile for patients affected by ARI.

References:

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