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## *Nigella sativa* L. in bronchial asthma - outcomes of a phase II clinical trial and effects on cytokines

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**Introduction:** Long-term medications in patients with asthma are needed to control the underlying inflammation and prevent symptoms. However, asthma control is considered to be suboptimal regardless of the availability of conventional treatments. Traditionally, *Nigella sativa* L. (NS), known as black cumin seed, is thought to be effective in treating asthma or its key symptoms. We investigated the benefits of NS supplementation on clinical and inflammatory parameters of bronchial asthma in patients on standard therapy.

**Materials & Methods:** A chemically characterized NS oil product (Marnys®) marketed as a food supplement was used in a randomized, double-blind, placebo-controlled, phase II trial (RDBPCT) with asthma patients. The primary outcome was the Asthma Control Test (ACT). The secondary outcomes were percentage of predicted forced expiratory volume in one second (predicted FEV1%), blood eosinophils, serum total Immunoglobulin E (IgE), and multiple inflammatory cytokines. Statistical independent t-test and Mann-Whitney U tests were used.

**Results & Discussion:** Between Jun 1 and Dec 30, 2015, 80 patients were enrolled, with 40 patients each randomly assigned to treatment and placebo groups. After 4 weeks, 10 patients had withdrawn from each group. NS showed a statistically significant improvement in Asthma Control Test score 21.1 (SD=2.6) versus 19.6 (SD=3.7) (p=0.044) and a significant reduction in blood eosinophils count by -50 (IQR=-155 to -1) versus 15 (IQR=-60 to 87) cells/ $\mu$ L (p=0.013). NS group had non-significant elevation of predicted FEV1% by 4 (IQR=-1.25 to 8.75) versus 1 (IQR=-2 to 5) (p=0.170). Elevated levels of serum INF-gamma, IL-10, and IL-12p70 cytokines were observed in NS group.

**Conclusions:** NS appeared to improve asthma symptoms control and, some asthma-related biomarkers. There is a potential for NS to be an effective complementary treatment in asthma. However, future longer and larger multicenter studies are required to establish a stronger evidence for the clinical use of NS in patients with asthma.

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