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Double-blind randomized placebo-controlled trial on efficacy and safety of *Lactuca sativa* L. seeds on pregnancy-related insomnia

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Abstract

Ethnopharmacological relevance: There is limited evidence about the role of herbal and traditional medicine in pregnancy-related insomnia. Extant documents on traditional Persian medicine refer to many plants which could induce sleep and which were used by pregnant women. In Iran, local herbal shops continue to provide these herbs to pregnant women to treat insomnia. One such herb is *Lactuca sativa* L. The aim of this study was to evaluate the effects of lettuce seed on pregnant women for the treatment of insomnia.

Methods and materials: In a prospective randomized clinical trial, 100 pregnant women with insomnia aged 20-45 years were assigned to receive capsules containing 1000 mg of lettuce seed or a placebo daily for two weeks. The main outcome was the quality of sleep, which was measured using the Pittsburgh Sleep Quality Index (PSQI).

Results: Each group contained 50 participants. An improvement in the PSQI score was significantly greater in patients receiving lettuce seed than those receiving the placebo. Linear regression analysis showed that, after controlling for the other variables, the average sleep score of the experimental group was significantly lower than for the placebo group ($p = 0.03$).

Conclusions: The findings of this study suggest that lettuce seed decreased insomnia during pregnancy and could be recommended as a safe natural remedy for treatment of pregnancy-related insomnia.

Keywords: Herbal medicine; Hypnotic; Insomnia; Pregnancy.

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