

Comparison of *Crocus sativus* L. and Fluoxetine in Treatment of Mild to Moderate Postpartum Depression: A Double-Blind Clinical Trial

Postpartum depression is a psychiatric disorder, defined as a subtype of major depressive disorder. It has been reported that 10-15% of women suffer postpartum depression following childbirth. Postpartum depression can harm the mother and child relationship, which in turn negatively impacts children in terms of nutrition and care, as well as physical and mental development. Plant extracts are some of the most attractive sources of new drugs and have shown promising results for treatment of depression. Saffron is produced from the tiny, dried stigma of lily-like *Crocus sativus* blossom. Genuine saffron is worth its weight in gold. In Asian medicine and in particular Persian traditional medicine, it is used to treat menstrual disorder, difficult labor, inflammation, vomiting and diseases affecting the throat. *Crocus sativus* is also used to treat depression. Several controlled and uncontrolled studies have shown its beneficial antidepressant and anti-dementia effects (1, 2). Our objective was to compare the efficacy of *Crocus sativus* with fluoxetine in treatment of mild to moderate postpartum depression in a 6-week, double-blind, randomized clinical trial. A 6-week, multicenter, randomized, double blind, parallel group clinical trial was conducted in the outpatient clinics of three teaching hospitals affiliated to Tehran University of Medical Sciences. Sixty-eight women between 18 to 45 years of age, with a diagnosis of postpartum depression based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision criteria were eligible to participate in the trial. *Patients were required to have mild to moderate postpartum depression at time of randomization, having a score ≤ 18 in the 17-item Hamilton Depression Rating Scale (HDRS).* Exclusion criteria included: women with psychotic depression, history of suicidal, a history of bipolar disorder, substance or alcohol dependence (with the exception of nicotine dependence), hypothyroidism and acute medical illness. Patients were randomized to receive either fluoxetine (40 mg/day) or saffron (30 mg/day) (SaffroMood®; IMPIRAN) capsule for six weeks. Participants were evaluated by Hamilton Depression Rating Scale (HDRS) at weeks 3 and 6 and their side effects were systematically recorded. The trial protocol was approved by the institutional review board (IRB) of Tehran University of Medical Sciences and performed in accordance with the Declaration of Helsinki and its subsequent revisions. The effect of time \times treatment interaction was assessed by general linear model repeated measures considering the treatment group (fluoxetine vs. saffron) as the between-subject factor and HDRS scores at each time point as the within-subject variables (time). Baseline HDRS scores were not significantly different between the saffron and the fluoxetine groups (16.53 ± 1.48 vs. 16.65 ± 1.12 , respectively, [MD (95% CI) = -0.12 (-0.78 to 0.53), $t(57.84) = -0.38$, $p = 0.70$]). General linear model repeated measures demonstrated insignificant effect for time \times treatment interaction on HDRS score [F (4.90, 292.50) = 1.04, $p = 0.37$]. Patients in the fluoxetine group experienced more headache, dry mouth, daytime drowsiness, constipation and sweating than the saffron group. However, frequencies of adverse events were not significantly different between the two groups. The results of this study emphasize efficacy of saffron in treatment of postpartum depression. On the other hand, the fewer side effects of saffron compared with the classical antidepressant, confirm application of saffron as an alternative treatment of depression in traditional medicine.

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