

Crocus sativus L. (saffron) in the treatment of premenstrual syndrome: a double-blind, randomised and placebo-controlled trial

M Agha-Hosseini,^a L Kashani,^b A Aleyaseen,^a A Ghoreishi,^c H Rahmanpour,^d AR Zarrinara,^e S Akhondzadeh,^f

- a Infertility Center of Dr Shariati Hospital, Vali Asr Reproductive Health Research Center, Tehran University of Medical Sciences, Tehran, Iran
- b Department of Reproductive Immunology, Reproductive Biotechnology Research Center, Avicenna Research Institute, ACECR, Tehran, Iran
- c Department of Psychiatry and d Department of Gynecology and Obstetric, Zanjan University of Medical Sciences, Zanjan, Iran
- e Division of Statistics and Information, Vice Chancellor for Research, Tehran University of Medical Sciences, Tehran, Iran
- f Psychiatric Research Center, Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences, Tehran, Iran

Introduction:

Several line of evidence point to a significant role of the serotonergic system in the course of the luteal phase in women with PMS. Moreover, the effect of sex hormones on serotonin uptake, binding, turnover and transport has also been indicated.

For this reason, it has been suggested that it is the dysregulation of the serotonergic system, which is responsible for the majority of PMS symptoms.

It has been reported that saffron through a serotonergic mechanism shows an antidepressant effect in the treatment of women with mild to moderate depression. Moreover, there is an overlap between the symptoms of depression and those associated with PMS.

Method: Women were randomly assigned to receive capsule saffron 30 mg/day (15 mg twice a day; morning and evening) (group A) or capsule placebo (twice a day) for a two menstrual cycles (cycles 3 and 4).

Participants: Women aged 20–45 years with regular menstrual cycles and experience of PMS symptoms (according to the current diagnostic criteria proposed by the American College of Obstetrics and Gynecology) for at least 6 months were eligible for the study.

The exclusion criteria were as follows: pregnancy or lactation, menstrual cycle irregularity, unstable medical illness, seizure disorder within the past year, history of multiple drug reaction, menstrual cycle length shorter than 24 days or longer than 35 days, major psychiatric disorder, suicidal ideation or intent, use of psychoactive drugs, investigational drugs or specific medication for PMS in the past 2 month, hormonal method of contraception and history of substance abuse in the previous 6 months.

Main outcome measures: The primary outcome measure was the Daily Symptom Report, and secondary outcome measure was the Hamilton Depression Rating Scale.

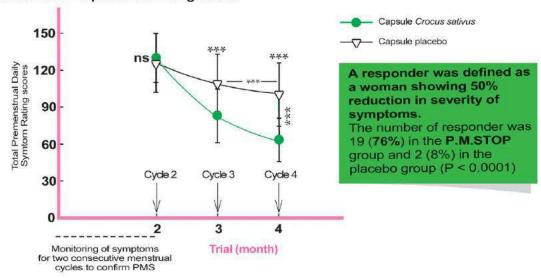


Fig. 1. Mean ± SD scores of two groups of women on the Total Premenstrual Daily Symptoms scores. NS, nonsignificant and ****P < 0.001. The horizontal symbols (***) were used to express statistical significance versus their respective baseline value and vertical symbols (*) were used for between-group comparisons.

Although all participants had been diagnosed with PMS by their gynaecologist, they were interviewed again for two menstrual cycles (premenstrual stage) before medication started to complete baseline Daily Symptom Ratings Report and Hamilton Depression Rating Scale and reconfirmation for diagnosis of PMS.

Measurements

The primary outcome measure was the Daily Symptom Report, a checklist of 17 premenstrual symptoms rated from 0 to 4 according to their severity throughout the menstrual cycle and consists four subscale including:

- pain (aches, cramps and tender breasts)
- mood (anxiety, irritability, depression, nervous tension, mood swings and out of control).
- behaviour (poor coordination, insomnia, confusion, headache, crying and fatigue) and
- physical (food craving and swelling) subscale.

Secondary outcome measure was Hamilton Depression Rating Scale (17-item).

Results:

In this trial, saffron was found to be effective in relieving symptoms of PMS. A significant difference was observed in efficacy of saffron in cycles 3 and 4 in the Total Premenstrual Daily Symptoms and Hamilton Depression Rating Scale.

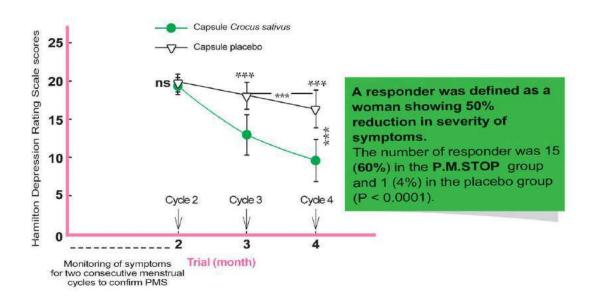


Fig. 2. Mean \pm SD scores of two groups of women on the Hamilton Depression Rating Scale scores. NS, nonsignificant and ***P < 0.001.

The horizontal symbols (***) were used to express statistical significance versus their respective baseline value and vertical symbols (‡) were used for between-group comparisons.

Conclusion:

The results of this study indicate the efficacy of C. sativus L. in the treatment of PMS.

The clinical relevance was emphasized by the improvements seen in the Total Premenstrual Daily Symptoms and the Hamilton Depression Rating Scale.





