Clinical Trials and Research of Saffron

Efficacy and safety of saffron as adjunctive therapy human with attention-deficit_hyperactivity

Hyperactivity Clinical Trials					
No	**Date**	**Saffron Compared with**	**Duration**	**Selected**	**Tested**
1	2022	Placebo	6 Week	106	56

Contents

1. Saffron in Phytotherapy: Pharmacology and clinical uses

Wiener Medizinische Wochenschrift (WMW) 2007; 157: 315-319

Mathias Schmidt, Georges Betti & Andreas Hensel

Themenschwerpunkt
Published: July 2007
Wien Med Wochenschr **157,** 315 (2007). https://doi.org/10.1007/s10354-007-0428-4

Summary:

Saffron (stigmates of Crocus sativus L.) has been used for medicinal purposes for millenaries. Throughout history, uses against cancer and depressive mood can regularly be identified. These applications have also been in the focus of modern research. Promising and selective anti-cancer effects have been observed in vitro and in vivo, but not yet in clinical trials. Antidepressant effects were found in vivo and in clinical pilot studies. Saffron extracts thus have the potential to make a major contribution to rational phytotherapy.

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2. Crocus sativus L. Versus Methylphenidate in Treatment of Children with Attention-Deficit/Hyperactivity Disorder: A Randomized, Double-Blind Pilot Study

Journal of Child and Adolescent Psychopharmacology
Published by Mary Ann Liebert

- ***February 2019***
- ***Journal of Child and Adolescent Psychopharmacology 29(3)***

Abstract and Figures

Objective:

Attention-deficit/hyperactivity disorder (ADHD) is one of the most common neuropsychiatric disorders of childhood and adolescence. About 30% of patients do not respond to stimulants or cannot tolerate their side effects. Thus, alternative medication, like herbal medicine, should be considered. The aim of this trial is to compare the safety and efficacy of Crocus sativus (saffron) versus methylphenidate in improving symptoms of children with ADHD. Methods: In a 6-week randomized double-blind study, 54 patients (children 6-17 years old) with a Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnosis of ADHD were randomly assigned to receive either 20-30 mg/d (20 mg/d for <30 kg and 30 mg/d for >30 kg) methylphenidate (MPH) or 20-30 mg/d saffron capsules depending on weight (20 mg/d for <30 kg and 30 mg/d for >30 kg). Symptoms were assessed using the Teacher and Parent Attention-Deficit/Hyperactivity Disorder Rating Scale-IV (ADHD-RS-IV) at baseline and weeks 3 and 6. Results: Fifty patients completed the trial. General linear model repeated measures showed no significant difference between the two groups on Parent and Teacher Rating Scale scores (F = 0.749, df = 1.317, p = 0.425, and F = 0.249, df = 1.410, p = 0.701, respectively). Changes in Teacher and Parent ADHD Rating Scale scores from baseline to the study end were not significantly different between the saffron group and the MPH group (p = 0.731 and p = 0.883, respectively). The frequency of adverse effects was similar between saffron and MPH groups. Conclusion: Short-term therapy with saffron capsule showed the same efficacy compared with methylphenidate. Nevertheless, larger controlled studies with longer treatment periods are necessary for future studies.

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3. Efficacy and safety of saffron as adjunctive therapy in adults with attention-deficit_hyperactivity disorder_ A randomized, double-blind, placebo-controlled clinical trial – ScienceDirect

Advances in Integrative Medicine

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- ***Version of Record 17 March 2022.***

Abstract:

Objective

Around 30% of patients with Attention-Deficit/Hyperactivity Disorder (ADHD) do not respond to Ritalin or cannot tolerate its side effects, which necessitates the consideration of alternative options. Previous studies have shown the beneficial effects of Crocus sativus (saffron) in children with ADHD. However, its potential therapeutic effects in adults with ADHD is unknown. This study aimed to evaluate the efficacy and safety of saffron as an adjuvant to Ritalin for improving symptoms in adults with ADHD.

Design

This was a randomized, double-blind, placebo-controlled clinical trial.

Methods

Fifty-six patients diagnosed with ADHD were assigned into two parallel groups to receive Ritalin (30 mg/day) plus placebo or Ritalin plus saffron (15 mg twice daily) for six weeks. The patients were assessed with Conners' Adult ADHD Rating Scales (CAARS) and the Adult ADHD Self-Report Scale (ASRS) at baseline, week 3 and week 6.

Results

Forty-four patients completed the trial. GLM repeated-measure analysis demonstrated significant time × treatment interaction effect for ASRS (df=2, F=3.455, and P-value=0.036) and CAARS (df=1.584, F=3.939, and P-value=0.033) score from baseline to the study endpoint. We found a significantly greater reduction in ASRS scores in the saffron group compared with the placebo group from baseline to the study endpoint (week 6) (P-value=0.024). However, the change score from baseline to week 3 was not significantly different between trial groups (P-value=0.269). There was no significant difference in the improvement of CAARS scores between saffron and placebo from baseline to week 3 or 6 (P-value=0.564 and 0.089, respectively). There was no significant difference between the two groups in baseline parameters and frequency of side effects.

Conclusions

Saffron combination therapy with Ritalin can effectively improve symptoms of patients with ADHD. However, further studies with larger sample sizes and longer follow-up treatment are needed to confirm our findings.

This trial was registered with the Iranian Registry of Clinical Trials (www.irct.ir; No IRCT20090117001556N111).