

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Saffron versus Methylphenidate in the treatment of Attention Deficit/ Hyperactivity Disorder: a double-blind and randomized trial

Protocol summary

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Summary

The aim of the present study is to evaluate the efficacy of saffron on ADHD in children and adolescents through a double-blind, randomized, controlled trial. 40 outpatients, including 6-17 years old who clearly meet the DSM-5 diagnostic criteria for ADHD(based on diagnosis of a child psychiatrist) will be randomly assigned to receive saffron Capsules (20 mg per day); methylphenidate (0.4 to 1 mg per day) or placebo for 6 weeks. The primary outcome measure is the Teacher and Parent ADHD Rating Scale. Patients will be assessed by a child psychiatrist at baseline, third and sixth weeks after the medication started.

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701131556N94**

Registration date: **2017-01-13, 1395/10/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-13, 1395/10/24

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of
Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

Scientific title

Saffron versus Methylphenidate in the treatment of
Attention Deficit/ Hyperactivity Disorder: a double-blind
and randomized trial

Public title

Saffron versus Methylphenidate in the treatment of
Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of ADHD based on DSM-5;
age between 6-17 years old. Exclusion criteria:
Intellectual disability; presence of any psychiatric
disorders except for ODD; history of allergy to saffron or
Ritaline; presence of any medical problem including
cardiovascular diseases; presence of uncontrolled
seizures; systolic blood pressure more than 120 mm Hg;
resting pulse rate less than 60/minute or more than
115/minute; receiving warfarin, ASA and other
antiplatelete agents; receiving any herbal medicine
including fever few, garlic, ginseng, dong quai, and red
clover; 14 days before any surgery; nursing and
pregnancy

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshvarz Blvd.

City

Tehran

Postal code**Approval date**

2016-12-21, 1395/10/01

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1203

Health conditions studied**1****Description of health condition studied**

Disturbance of activity and attention

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes**1****Description**

Severity of ADHD

Timepoint

Week 0 (before treatment) and Weeks 3 and 6 after treatment

Method of measurement

Teacher and Parent ADHD Rating Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Ritaline 0.4 to 1 mg per day and placebo as control group for 6 weeks

Category

Treatment - Drugs

2**Description**

Capsule Saffron 20 mg per day as intervention group for 6 weeks

Category

Treatment - Drugs

3**Description**

Capsule placebo 20 mg per day as intervention group for 6 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Roozbeh Hospital, South Kargar Sreet

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Yunesian

Street address

Tehran University of Medical Sciences, Keshvarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty