Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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 duiagnosis 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.

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

s.akhond@sina.tums.ac.ir

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

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 Sreeet
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