

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Saffron (*crocus sativus*) for attention deficit hyperactivity disorder in adults: a double blind and placebo controlled trial

Protocol summary

Study aim

The aim of the present study is to evaluate the efficacy of saffron on ADHD in adults through a double-blind, randomized, controlled trial

Design

Randomized, double-blind, placebo controlled study

Settings and conduct

The study will be conducted among patients attending Roozbeh Hospital-Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of ADHD based on DSM-5; age between 20-60 years old. Exclusion criteria: chronic medical disease including seizure, cardiovascular disease, CVA and organic brain disease; substance abuse or dependence during past six months; nursing or pregnant patients; history of tic disorder; receiving of any psychotropics drugs during past two weeks; mental retardation ; history of suicide attempt, psychosis or aggressiveness; receiving psychotropic drugs; receiving psycho-stimulants or atomoxetine during past three months; bipolar disorder.

Intervention groups

Intervention group: capsule saffron 15 mg BID plus ritaline (methylphenidate) 30 mg per day for 6 weeks. Control group: capsule placebo plus tab. ritaline 30 mg per day for 6 weeks.

Main outcome variables

Severity of ADHD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N111**

Registration date: **2018-07-25, 1397/05/03**

Registration timing: **prospective**

Last update: **2018-07-25, 1397/05/03**

Update count: **0**

Registration date

2018-07-25, 1397/05/03

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

Expected recruitment start date

2018-08-05, 1397/05/14

Expected recruitment end date

2020-08-04, 1399/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Saffron (*crocus sativus*) for attention deficit hyperactivity disorder in adults: a double blind and placebo controlled trial

Public title

saffron for attention deficit hyperactivity disorder in adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of ADHD based on DSM-5 Age between 20-60 years old

Exclusion criteria:
Chronic medical disease including seizure, cardiovascular disease, CVA and organic brain disease Substance abuse or dependence during past six months Nursing or pregnant patients History of tic disorder Receiving of any psychotropics drugs during past two weeks, Intellectual disability History of suicide attempt, psychosis or aggressiveness Receiving psycho-stimulants or atomoxetine during past three months Bipolar disorder

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Permuted block

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, clinicians and outcome evaluators will be blind regarding grouping

Placebo
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, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.TUMS.VCR.REC.1397.259

Health conditions studied

1

Description of health condition studied

Disturbance of activity and attention

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Severity of ADHD

Timepoint

Baseline (before treatment) and weeks: 3 and 6 after treatment

Method of measurement

By adult ADHD Self-Report Scale and Conners Adult ADHD Rating Scales-Self-Report-screening version

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule saffron 15 mg BID plus Tab. ritaline (methylphenidate) 30 mg per day for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Capsule placebo plus tab. ritaline (methylphenidate) 30 mg per day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

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Roozbeh Hospital, South Kargar Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

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
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data will be distributed through final report

When the data will become available and for how long

from 2021 to 2026

To whom data/document is available

En academic researchers

Under which criteria data/document could be used

All users should cite the source of data

From where data/document is obtainable

prof Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

Comments