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 ofsaffron 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 fo 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
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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

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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
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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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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