Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Comparing the effect of saffron extract with methylphenidate on impulsivity and attention deficit scores in 6-12-year-old children with attention deficit hyperactivity disorder

Protocol summary

Study aim
Comparing the effect of saffron extract with methylphenidate on impulsivity and attention deficit scores in 6-12-year-old children with attention deficit hyperactivity disorder

Design
Clinical trial with control group, with parallel groups, randomized, phase 2 on 60 patients. A table of random numbers will be used for randomization.

Settings and conduct
Study population: 6-12-year-old children with attention deficit hyperactivity disorder; Place of study: Child and Adolescent Psychiatry Clinic, Ibn Sina Hospital, Mashhad; Blinding: Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at the age of 6 to 12 years, Hyperactivity Disorder, informed consent of parents, IQ in the normal range. Exclusion criteria: Suffering from any type of systemic or psychiatric disease or other psychiatric disorders that require medication

Intervention groups
Intervention group: In addition to treatment with methylphenidate for 6 weeks, children under 30 kg will receive Etansaf capsules containing ten milligrams of dry saffron extract twice a day and children over 30 kg three times a day. Control group: Patients will only be treated with the required drug (methylphenidate) for the disorder.

Main outcome variables
Impulsivity score based on a questionnaire, attention deficit score based on a questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101130005280N63**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date
2023-12-18, 1402/09/27

Registrant information

Name
Raheleh Nejati

Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-02, 1402/10/12

Expected recruitment end date
2024-03-31, 1403/01/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of saffron extract with

methylphenidate on impulsivity and attention deficit scores in 6-12-year-old children with attention deficit hyperactivity disorder

Public title
Comparing the effect of saffron extract with methylphenidate in hyperactivity disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range between 6-12 years Diagnosis of attention deficit hyperactivity disorder based on DSM-5 criteria Informed parental consent IQ in the normal range (based on interviews and previous records) Not having a clear organic disease (based on the history obtained from the patient's family) Not suffering from other psychiatric disorders (based on a structured interview conducted by a specialist in child and adolescent psychiatry)
Exclusion criteria:
Suffering from any type of systemic or psychiatric disease or other psychiatric disorders that require medication Impossibility of examining the patient carefully due to unavailability Substance dependence
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 60 patients are randomized simply using a table of random numbers. To use the table of random numbers, first, the framework of the statistical community is determined (60 people); respectively, we give them a code or serial number. Codes and numbers should be equal to that assigned to the members of society; for example, in our research, we give two-digit codes to people, such as 01, 02, 03, ..., 11, 12,... To select sample people from the table, we randomly start from a point in the row or column direction. We can choose the point by closing our eyes and placing a finger or pen tip on the table. Moving in the row or column direction does not differ and is optional. But according to the type of code digits (one digit, two digits, three digits, etc.), we must choose the same number of digits in the direction of a row or column. After this, we control the route numbers. Whether we like it or not, we will come across two types of numbers, one smaller than the number of the studied community and the other larger than the number of the community. We should pay attention to and choose only the smaller numbers. The selected number is the code of an individual from the community chosen as a sample. This work should continue until the sample people can be selected as small as possible. After the sample volume is complete, the sampling work ends. The numbers will be placed in sealed envelopes, and when the participants enter, an envelope will be assigned to each of them, and they will be placed in one of the two intervention groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2023-11-20, 1402/08/29
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.386

Health conditions studied

1

Description of health condition studied
Attention deficit hyperactivity disorder (ADHD)
ICD-10 code
F90.9
ICD-10 code description
Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description
Impulsivity score
Timepoint
At the beginning of the study and 6 weeks later
Method of measurement
by Connors parent questionnaire to evaluate attention deficit hyperactivity disorder

2

Description
Attention deficit score
Timepoint
At the beginning of the study and 6 weeks later
Method of measurement
by Connors parent questionnaire to evaluate attention deficit hyperactivity disorder

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to treatment with methylphenidate for 6 weeks, children under 30 kg will receive Etansaf capsules containing ten milligrams of dry saffron extract twice a day and children over 30 kg three times a day.
Category
Placebo

2

Description
Control group: Patients in the control group will be treated with usual drugs (methylphenidate) twice a day
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina Psychiatric Hospital
Full name of responsible person
Fatemeh Moharrari
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Ibn Sina Psychiatric Hospital, Bu Ali Square, Mashhad
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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Asieh Hosseinpour
Position
Associate
Latest degree
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Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Assistant Professor, Child and Adolescent Psychiatrist, Head of Ibn-e-Sina Hospital & Hejazi Hosoita

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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Assistant Professor, Child and Adolescent Psychiatrist, Head of Ibn-e-Sina Hospital & Hejazi Hosoita

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available