

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 Sciences, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

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

Street address

Ibn Sina Psychiatric Hospital, Bu Ali Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 903 926 4520

Email

raikaravan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 -91357

Phone

+98 903 926 4520

Email

raikaravan@gmail.com

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

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Ibn Sina Psychiatric Hospital, Bu Ali Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 903 926 4520

Email

seyedhosseinkhademi1401@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Fatemeh Moharari

Position

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

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,
Boo Ali square

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 71 12721

Fax

+98 51 1712 4184

Email

mohararif1@mums.ac.ir

Web page address**Latest degree**

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Ibn-e-Sina psychiatric Hospital, Horre ameli avenue,
Boo Ali square

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 71 12721

Fax

+98 51 1712 4184

Email

mohararif1@mums.ac.ir

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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Fatemeh Moharari

Position

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