

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effectiveness of Persian Medicine products, common figs and almonds syrup, sweet almond syrup and methylphenidate in the treatment of attention deficit / hyperactivity disorder: A randomized double-blind clinical trial

#### Protocol summary

##### Study aim

Comparison of the effectiveness of Persian Medicine products, common figs and almonds syrup, sweet almond syrup and methylphenidate in the treatment of ADHD

##### Design

The study is a double blinded Block Randomized Clinical Trial and the target group of children with ADHD are 6-14 years who receive methylphenidate at a constant dose throughout the study. There are two intervention groups receiving either sweet almond or common figs and almonds syrup with methylphenidate and the control group receive placebo and methylphenidate with a sample size of 120 (40 for each group).

##### Settings and conduct

Design is double blinded block randomized (patient and researcher are unaware of the type of intervention and only the coordinator is informed). The ADHD rating scale questionnaires are completed by the teacher and parents before the intervention, as well as the demographic questionnaire and clinical examinations. After starting the project, the patient is followed up every four weeks for 12 weeks by completing questionnaires.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 6 to 14 years old with ADHD according to the psychiatrist diagnosis based on DSM5 criteria, methylphenidate use and no other drugs. Exclusion criteria: concomitant use of other alternative and complementary medicine methods; mental retardation; medical illness; other mental disorders; organic brain problem; malnutrition and obvious growth disorders; recent treatment with antipsychotic drugs; drug dependence or abuse; history of allergies to sweet almonds and figs and their products; the need for behavioral therapy.

##### Intervention groups

There are 3 groups in this study. These include: 1- placebo + methylphenidate; 2- sweet almond syrup +methylphenidate; 3- common figs and almonds syrup + methylphenidate

##### Main outcome variables

The score obtained from the ADHD rating scale questionnaire

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220406054433N1**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

##### Registration date

2022-04-23, 1401/02/03

##### Registrant information

##### Name

Alireza Mahjoub

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8808 2213

##### Email address

mahjoub.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2022-04-21, 1401/02/01

**Expected recruitment end date**

2022-12-22, 1401/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of Persian Medicine products, common figs and almonds syrup, sweet almond syrup and methylphenidate in the treatment of attention deficit / hyperactivity disorder: A randomized double-blind clinical trial

**Public title**

Effect of common figs and almonds syrup, sweet almond syrup and methylphenidate in the treatment of attention deficit / hyperactivity disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Children 6 to 14 years old suspected to ADHD Obtain informed consent from the child's parent or guardian Diagnosis of ADHD by a psychiatrist New diagnosis of the disorder and not taking another drug

**Exclusion criteria:**

Mental retardation IQ <70 Simultaneous use of other methods of alternative and complementary medicine Having medical conditions including cardiovascular disease, gastrointestinal diseases, epilepsy Having other mental disorders including schizophrenia Existence of an organic brain problem Malnutrition and obvious growth disorders Recent treatment with antipsychotic drugs Drug dependence or abuse in the last 6 months History of allergies to sweet almonds and its products History of allergies to figs and its products Simultaneous consumption of other products containing almonds (nuts, almond sweets) and figs The need for behavioral therapy

**Age**From **6 years** old to **14 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**Target sample size: **120****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of patients will be done by randomized blocks using online sealed envelope software and 6

blocks of equal size, and patients will be randomly divided into one of three groups. Groups are identified and coded as A, B, C, and the prescriber and the recipient are unaware of this. Only the coordinator knows who in which group and which group received which treatment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The method of blinding the study will be that the drugs and placebo studied, including Ritalin tablets, sweet almond syrup, almond and fig syrup and ineffective syrup are packed in similar containers. The drug is given to the patient based on randomized sequences. And so the examiner and the patient are blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Iran University of Medical Sciences

**Street address**

5th floor, Headquarters Building, Iran University of Medical Sciences, Hemmat Highway next to Milad Tower

**City**

Tehran

**Province**

Tehran

**Postal code**

14496164535

**Approval date**

2022-03-16, 1400/12/25

**Ethics committee reference number**

IR.IUMS.REC.1400.1264

**Health conditions studied****1****Description of health condition studied**

Attention-deficit hyperactivity disorder

**ICD-10 code**

F90.0

**ICD-10 code description**

Attention-deficit hyperactivity disorder, predominantly inattentive type

## Primary outcomes

### 1

#### Description

Severity of attention deficit / hyperactivity disorder based on the questionnaire score

#### Timepoint

At the beginning of the study (before the intervention), 4, 8 and 12 weeks after starting the drug

#### Method of measurement

Teacher and Parent ADHD rating scale

## Secondary outcomes

### 1

#### Description

Evaluation of drug side effects

#### Timepoint

Once every 2 weeks after starting treatment

#### Method of measurement

Checklist of drug side effects and possible side effects based on CTCAE criteria (Common Terminology Criteria for Adverse Events v4.03, 2010)

### 2

#### Description

BMI, and clinical examination results

#### Timepoint

4, 8 and 12 weeks after the start of the intervention

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Control group: The first group, they will receive the standard drug methylphenidate (Ritalin) with the dose of 1 mg / kg / day, In the first week (1.2 in the morning, 1.2 in the afternoon) and from the second week onwards (1 in the morning and 1 at noon) and if the patient weighs more than 30 kg, from the second week 3 tablets daily (1 Morning, 1 at noon and 1 at 4 pm). And a simple ineffective syrup as a placebo with the dose of 5 cc, three times a day. The simple syrup is made in the Pharmacy Department of the School of Traditional Medicine, Iran University of Medical Sciences according to British Pharmacopoeia. The duration of use is 12 weeks

#### Category

Placebo

### 2

#### Description

Intervention group: The second group, they will receive the standard drug methylphenidate (Ritalin) with the dose of 1 mg / kg / day, In the first week (1.2 in the

morning, 1.2 in the afternoon) and from the second week onwards (1 in the morning and 1 at noon) and if the patient weighs more than 30 kg, from the second week 3 tablets daily (1 Morning, 1 at noon and 1 at 4 pm). And sweet almond syrup at a dose of 5CC three times a day for 12 weeks. Sweet Almond Syrup is a syrup made in the Department of Pharmacy of the School of Persian Medicine, Tehran University of Medical Sciences, which is made of sweet almonds and raisins. This drug is currently available in the pharmaceutical market of Schools of Persian Medicine.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: The third group, they will receive the standard drug methylphenidate (Ritalin) with the dose of 1 mg / kg / day, In the first week (1.2 in the morning, 1.2 in the afternoon) and from the second week onwards (1 in the morning and 1 at noon) and if the patient weighs more than 30 kg, from the second week 3 tablets daily (1 Morning, 1 at noon and 1 at 4 pm). And Almond and fig syrup made by NIAK company with registration number 8953162594580741 in the Food and Drug Administration of the Islamic Republic of Iran. This drug is currently available in the pharmaceutical market of Schools of Persian Medicine.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Complex

##### Full name of responsible person

Mohammad Effatpanah

##### Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 0213

##### Email

m-effatpanah@tums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Children's Medical Center

##### Full name of responsible person

Mohammad Effatpanah

**Street address**

Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

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**Title of funding source**

Iran 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

**3****Recruitment center****Name of recruitment center**

Ziaeian hospital

**Full name of responsible person**

Mohammad Effatpanah

**Street address**

Ziaeian hospital, Abuzar Sq, Qazvin Street.

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**Province**

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1366736511

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**Email**

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**Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Alireza Mahjoub

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Behesht street, School of traditional medicine

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**Province**

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**Postal code**

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**Phone**

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**Email**

ali\_r\_mahjoub@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Majid Dadmehr

**Street address**

Behesht street-School of traditional medicine

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**Web page address**

http://iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hoorieh Mohammadi Kenari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Alireza Mahjoub

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Behesht street, School of traditional medicine

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ali\_r\_mahjoub@yahoo.com

**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**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Comparison of quantitative changes before and after the intervention is examined

**When the data will become available and for how long**

1 year after the article was published

**To whom data/document is available**

Not planned

**Under which criteria data/document could be used**

Not planned

**From where data/document is obtainable**

Not planned

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

Not planned

**Comments**