

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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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

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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

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Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

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2

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

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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**

Ziaeeian hospital

Full name of responsible person

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

Iran University of Medical Sciences

Full name of responsible person

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

Yes

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

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

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Full name of responsible person

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

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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

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