Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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

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Alireza Mahjoub

Name of organization / entity

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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
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
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2

Recruitment center
Name of recruitment center
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3

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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

Person responsible for general inquiries

Contact
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Iran University of Medical Sciences
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Alireza Mahjoub
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Resident
Latest degree
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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