Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Sweet almond syrup, Iranian Traditional Medicine product, compared with methylphenidate for Attention-Deficit/Hyperactivity Disorder in children: triple-blind randomized Clinical trial

Protocol summary

Summary

The purpose of this study is to evaluate the effect of Sweet almond syrup for Attention-Deficit/Hyperactivity Disorder in children. The study is a randomized, triple-blind and single-center which will be carried out on 50 patients with combined subtype ADHD referred to Ziaeian Hospital. The study will be conducted on children with 6 to 14 years, Has been diagnosed by a child psychiatrist and not received any other treatment yet and has no other mental or physical illness at the same time and will be excluded if side effects and drug intolerance occurs. Method: with simple randomization, Patients will be divided into 2 groups: Intervention Group (sweet almond syrup and an ineffective tablet as placebo) and Control Group (Ritalin and an ineffective syrup as placebo). Patients will be treated for 8 weeks and will be visited in the first day and then weeks 2, 4, 6 and 8 after starting the drug and the response to treatment and possible side effects are examined by the relevant examination and questionnaire.

General information

Acronym

Attention-Deficit/Hyperactivity Disorder : ADHD

IRCT registration information

IRCT registration number: **IRCT2015050922165N1**
Registration date: **2015-07-14, 1394/04/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-07-14, 1394/04/23

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran university of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Sweet almond syrup, Iranian Traditional Medicine product, compared with methylphenidate for Attention-Deficit/Hyperactivity Disorder in children: triple-blind randomized Clinical trial

Public title

Effect of Sweet almond on ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 6 to 14 years; Combined subtype ADHD diagnosis by a psychiatrist; Obtain written informed consent from each patient's parent or guardian; No mental retardation (I.Q.>70); Non use of other Complementary and Alternative Medicine methods; No any significant chronic medical condition including cardiovascular disease, GI disorders, seizures; No other psychiatric disorder such as schizophrenia; No organic brain disorder; No clear developmental disorders and Malnutrition; no recent treatment with psychotherapic drugs; Not clinically current abuse or dependence on drugs within 6 months; New diagnoses of disorder and No other drug use; Not required behavior Therapy; No sensitivity to sweet almond and its products; Non-concurrent use of other products containing almonds (Nuts, nougat) Exclusion criteria: Symptoms of sensitivity to sweet almond; Intolerance sweet almond syrup; Complications increase in moisture in the body; Dissatisfaction of parents or patient; The risk of other mental illness that requires treatment during the study

Age

From **6 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Keshavarz Ave., Tehran

City

Tehran

Postal code

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.TUMS.REC.1394.195

Health conditions studied

1

Description of health condition studied

Attention-Deficit/Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

ADHD severity

Timepoint

weeks 2, 4, 6 and 8 after starting the drug

Method of measurement

Standard Teacher and Parent ADHD rating scale

Secondary outcomes

1

Description

adverse effect of sweet almond syrup (skin & respiratory sensitivity ...)

Timepoint

weeks 2, 4, 6 and 8 after starting the drug

Method of measurement

Questionnaire

2

Description

adverse effect of Ritalin (headache, abdominal pain, nausea, ...)

Timepoint

weeks 2, 4, 6 and 8 after starting the drug

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Group: Sweet almond syrup 5 cc/TDS and an ineffective tablet as placebo for 8 weeks

Category

Treatment - Other

2

Description
Control Group: Ritalin 1mg/kg/day and an ineffective syrup as placebo 5cc/TDS for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
Dr Mohammad Effatpanah, Child Psychiatrist
Street address
Opposite municipality 17, 20 m Abuzar, Abuzar Square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran university School of Traditional Medicine
Full name of responsible person
Dr. Roja Rahimi
Street address
College of Traditional Medicine of Tehran University of Medical Sciences, Giti Alley, Vafamanesh Street, Heravi Square, Pasdaran Street
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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
Vice Chancellor for research of Tehran university School of Traditional Medicine
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty