

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 Ziaieian 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

Monireh Sadat Motaharifard

Name of organization / entity

School of Traditional Medicine, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3333 6823

Email address

m-motaharifard@razi.tums.ac.ir

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 psychotherapeutic 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

City

Tehran

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Monireh sadat Motahari fard

Position

PhD Student of Traditional Medicine

Other areas of specialty/work

Street address

College of Traditional Medicine of Tehran University of Medical Sciences, Behesht Street, Vahdat Eslami Street

City

Tehran

Postal code

Phone

+98 21 5563 9724

Fax

Email

m-motaharifard@razi.tums.ir
monirehmotahari@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Nejatbakhsh

Position

PhD of Traditional Medicine

Other areas of specialty/work

Street address

College of Traditional Medicine of Tehran University of Medical Sciences, Behesht Street, Vahdat Eslami Street

City

Tehran

Postal code

Phone

+98 21 5563 9724

Fax

Email

nejatbakhsh@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Monireh sadat Motahari fard

Position

PhD Student of Traditional Medicine

Other areas of specialty/work

Street address

College of Traditional Medicine of Tehran University of Medical Sciences, Behesht Street, Vahdat Eslami Street

City

Tehran

Postal code**Phone**

+98 21 5563 9724

Fax**Email**

m-motaharifard@razi.tums.ir

Web page address**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