

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of diets on symptom control of attention deficit hyperactivity disorder in children

Protocol summary

Study aim

Determining the effect of diet on symptoms of quality of life, disability, cognitive and academic performance of children with attention deficit hyperactivity disorder

Design

This study will be conducted as a phase 3 clinical trial with a control group on children with attention deficit hyperactivity disorder. The study is single blind and will be conducted on 44 patients. The rand function of Excel software will be used for randomization

Settings and conduct

The participants are ADHD patiens under care in the children's department of Besat Hospital of Hamedan, who will be randomly assigned to intervention and control groups, the intervention group will be take atomoxetine drug with a diet containing vitamins of group B and vitamins C and iron and zinc minerals. The control group will receive Atomoxetine drug without nutritional intervention. Both groups will be followed for 8 months. Disease symptoms in two groups before and after the intervention will be evaluated with SWAN, Conners and SDQ questionnaires. The person who evaluating the symptoms at the end of the treatment will be blinded of the intervention and control groups.

Participants/Inclusion and exclusion criteria

The participants are 7-16-year-old children with attention-deficit-hyperactivity disorder who have a normal IQ. Children with neurological or organic disorders will not be included in the study

Intervention groups

The intervention group will be treated with 40 mg atomoxetine daily and a diet containing essential amino acids, vitamin groups and vitamin C, and iron and zinc minerals. The control group will only use atomoxetine 40 mg daily and the usual daily diet

Main outcome variables

The main outcome of studying will be the changes in the clinical symptoms of attention deficit hyperactivity disorder in the fields of quality of life, disability, cognitive

and academic performance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N25**

Registration date: **2022-12-15, 1401/09/24**

Registration timing: **prospective**

Last update: **2022-12-15, 1401/09/24**

Update count: **0**

Registration date

2022-12-15, 1401/09/24

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0097

Email address

a.moradi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of diets on symptom control of attention deficit hyperactivity disorder in children

Public title

The effect of diet on the symptoms of attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 7 to 16 years No neurological or organic disorder

Exclusion criteria:

Lack of compliance Patients on a special diet

Age

From **7 years** old to **16 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 44 cards and write letter I on 22 for intervention and on the other 22 letter C for the Control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and open it, based on selected letter (I or C) patients will be assigned to intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the symptoms of attention-deficit/hyperactivity disorder after the intervention will be blinded of the type of treatment regimen of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical

Science

Street address

Hamadan University of medical Science, Shahid Fahmideh Ave, Hamadan city, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838697

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.UMSHA.REC.140.756

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

attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes**1****Description**

Change in disease symptoms

Timepoint

Before starting treatment and 8 months after starting treatment

Method of measurement

with the SWAN and Conners questionnaires

Secondary outcomes**1****Description**

Changes in the child's strengths and weaknesses

Timepoint

Before and 8 months after treatment starting

Method of measurement

with the SDQ questionnaire

Intervention groups**1****Description**

Intervention group: Underwent atomoxetine (40 mg daily) and diet including essential amino acids, B vitamins, vitamin C and iron and zinc minerals Treatment

Category

Treatment - Other

2

Description

Control group: Treated with atomoxetine 40 mg without special diet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Afshin Faiazi

Street address

Besat hospital, Shahid Beheshti Blv, Hamadan city, Iran

City

Hamadan

Province

Hamadan

Postal code

6515974544

Phone

+98 81 3264 0030

Fax

+98 81 3265 1515

Email

Besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Reza Shokohi

Street address

Hamadan University of medical science, Shahid Fahmide Ave, Hamadan, Iran

City

Hamadan

Province

Hamadan

Postal code

6517838677

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

vc_research@umsha.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

shahid fahmideh street medical faculty

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0572

Fax

+98 81 3838 0208

Email

a.moradi@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Afshin Faiazi

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Medical school, Shahid Fahmideh Ave, Hamadan, Iran

City

Hamadan

Province

Hamadan
Postal code
6517838736
Phone
+98 81 3838 0572
Fax
+98 81 3838 0208
Email
Afshinfay@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
Coach
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Medical School, Shahid Fahmideh Ave, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code

6517838736
Phone
+98 81 3838 0572
Fax
+98 81 3838 0208
Email
a.moradi@umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available