

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Study of the efficacy and safety of vitamin D add-on standard treatment regimen for children with attention-deficit hyperactivity disorder in 7- to 14 year-Old : A 12 weeks randomized, open-label, parallel group Study

Protocol summary

Study aim

Evaluation of the efficacy and safety of vitamin D add-on standard treatment regimen for children with attention-deficit hyperactivity disorder(ADHD) and without vitamin D deficiency in 7- to 14 year-Old on the ADHD symptoms and growth status

Design

A randomized, open-label, controlled clinical trial, design of 38 patients with ADHD, between March and October 2017

Settings and conduct

Eligible patients referring to the pediatric psychiatric clinic of Zare hospital affiliated to Mazandaran University of Medical Sciences, Sari, or Roozbeh hospital affiliated to Tehran University of Medical Sciences, Tehran, are randomly divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 7-14 years old children with ADHD and without vitamin D deficiency Exclusion criteria: acute phase of the disease; underlying disease; mental retardation; any enriched products with vitamin D at least 2 months

Intervention groups

Subjects in the intervention group receive vitamin A+D drop with a dose of 400 unit/day for vitamin D along with standard therapeutic regimen and the control group receive standard therapeutic regimen alone for 12 weeks.

Main outcome variables

The scores of emotional and behavioral problems in Strengths and Difficulties Questionnaire, The scores of symptoms of hyperactivity, impulsivity and cognitive impairment of ADHD in Parent's Rutter Questionnaire, The scores of symptoms of hyperactivity, impulsivity and cognitive impairment of ADHD in Conners' Parent Rating Scale, Serum 25(OH) vitamin D level, Side effects of vitamin D

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120314009297N4**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

Registration date

2018-05-14, 1397/02/24

Registrant information

Name

narjes hendouei

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2017-10-23, 1396/08/01

Trial completion date

empty

Scientific title

Study of the efficacy and safety of vitamin D add-on standard treatment regimen for children with attention-deficit hyperactivity disorder in 7- to 14 year-Old : A 12 weeks randomized, open-label, parallel group Study

Public title

The effect of vitamin D on the treatment of symptoms in children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

7-14 years old children diagnosed attention deficit hyperactivity disorder children by two psychiatrists and based on DSM-V Without vitamin D deficiency (Serum 25(OH) vitamin D levels above 30ng/ml) All patients are on standard treatment regimen for attention-deficit hyperactivity disorder for at least 3 months and a stable dose for at least 1 month

Exclusion criteria:

Acute relapse Psychiatric comorbidity as defined by DSM-V Mental retardation Neurological diseases such as delirium, seizure, traumatic brain injury Current significant unstable medical illness Hypersensitivity to vitamin D Previous treatment with any products enriched with vitamin D at least 2 months before the initiation Unwillingness of the patient or his guardian to participate in the study

Age

From **7 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random numbers and 1: 1 ratio in treatment group and control group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Building No 2, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2017-06-06, 1396/03/16

Ethics committee reference number

IR.MAZUMS.REC.96.2829

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

The scores of emotional and behavioral problems in Strengths and Difficulties Questionnaire

Timepoint

At baseline and days 45 and 90 of the baseline

Method of measurement

Strengths and Difficulties Questionnaire (SDQ)

2

Description

The scores of symptoms of hyperactivity, impulsivity and cognitive impairment of ADHD in Parent's Rutter Questionnaire

Timepoint

At baseline and days 45 and 90 of the baseline

Method of measurement

Parent's Rutter questionnaire

3

Description

The scores of symptoms of hyperactivity, impulsivity and cognitive impairment of ADHD in Conners' Parent Rating Scale

Timepoint

At baseline and days 45 and 90 of the baseline

Method of measurement

Conners' Parent Rating Scale

4**Description**

Serum 25(OH) vitamin D level

Timepoint

At baseline and day 90 from baseline

Method of measurement

ELISA Kit

5**Description**

Side effects of vitamin D

Timepoint

At baseline and days 45 and 90 of the baseline

Method of measurement

Side effects checklist and Serum 25(OH) vitamin D level

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

Weight

Timepoint

At baseline and day 90 from baseline

Method of measurement

Scales

2**Description**

Waist circumference

Timepoint

At baseline and day 90 from baseline

Method of measurement

Tape

3**Description**

Body mass index

Timepoint

At baseline and day 90 from baseline

Method of measurement

Using the formula kilograms per square meter of height(Kg/m²)

4**Description**

Serum total cholesterol level

Timepoint

At baseline and day 90 from baseline

Method of measurement

Laboratory kit

5**Description**

Serum Low-density lipoprotein(LDL) level

Timepoint

At baseline and day 90 from baseline

Method of measurement

Laboratory kit

6**Description**

Serum High density lipoprotein (HDL) level

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

7**Description**

Serum triglyceride level

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

8**Description**

Serum fasting blood sugar level

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

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

Intervention group: receive vitamin A+D drop with a dose of 400 unit/day for vitamin D for 12 weeks along with their standard therapeutic regimen

Category

Treatment - Drugs

2**Description**

Control group: receive their standard therapeutic regimen alone for 12 weeks

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pediatric Psychiatric Clinic of Zare Hospital

Full name of responsible person

Narjes Hendouei

Street address

Zare Hospital, Taravat St., Neka Road

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2

Recruitment center

Name of recruitment center

Pediatric Psychiatric Clinic of Roozbeh hospital

Full name of responsible person

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Roozbeh hospital, District 11, Karegar St, No. 606

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name

Mazandaran University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Narjes Hendouei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Latest degree

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Person responsible for updating data

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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