Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 receivestandard 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)

Phone

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Email address

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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
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
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Building No 2, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran
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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
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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