Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Effect of vitamin D deficiency treatment on children with Attention deficit hyperactivity disorder (ADHD)

Protocol summary

Summary

Study design: Randomized, double-blind, placebo-controlled, single-center Study: Randomized clinical trial The sample number and sampling (Sampling): the target population of children with ADHD will be between 2 to 18 years.random sampling will be simple (Simple Random Sampling), which will be achieved through the generation of random numbers by computer.The number of samples calculated in 100 patients (50 in each group) will be. After sampling, by applying the inclusion and exclusion criteria from the study patients will be enrolled. Inclusion: children age between 2-18 years Exclusion: anticonvulsant, corticosteroids, supplements which contains vitamin D consumption. chronic disease. lower than normal range of ferritine. Blood samples taken from children with adhd diagnosed by child psychiatrist and vitamin D will be checked,we choose the people who are vitamin D deficient and randomly divided into two groups of test and control. 6Perl of vitamin D 50 000 IU given to test group and the control group will receive a placebo weekly for six weeks.After eight weeks of the study, vitamin D levels in all patients will be checked and the respond to the treatment of ADHD will be assessed by a child psychiatrist. Intervention time: about one year 2016.07.10 to 2017.07.11 The primary outcome of the study: vitamin D levels and response to treatment of ADHD out under the supervision of physician self-report questionnaire to evaluate the severity of symptoms of attention deficit hyperactivity Connors and recovery or non-recovery by the doctor

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012826998N2**
Registration date: **2017-03-01, 1395/12/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

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Recruitment status

Recruitment complete

Funding source

Drug Applied Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2016-07-10, 1395/04/20

Expected recruitment end date

2017-07-11, 1396/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D deficiency treatment on children with Attention deficit hyperactivity disorder (ADHD)

Public title

Effect of vitamin D deficiency treatment on children with Attention deficit hyperactivity disorder (ADHD)

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion: children age between 2-18 years Exclusion: anticonvulsant, corticosteroids, supplements which contains vitamin D consumption chronic disease
Age
From **2 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Ethic department, education building, Tabriz University Medical Sciences, Tabriz, Iran
City
Tabriz
Postal code
Approval date
2016-09-22, 1395/07/01
Ethics committee reference number
IR.TBZMED.REC.1395.556

Health conditions studied

1

Description of health condition studied
Attention deficit hyperactivity disorder (ADHD)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Vitamin D level
Timepoint
8 weeks
Method of measurement
blood sample

Secondary outcomes

1

Description
Factors related to severity of ADHD
Timepoint
8 weeks
Method of measurement
Coners checklist

Intervention groups

1

Description
In intervention group, 50000 IU pearl of vitamin D administered weekly for six weeks. The serum levels of vitamin D are evaluated at baseline and after eight weeks. The ADHD development is assessed by pediatrics psychologist at baseline and after eight weeks.
Category
Treatment - Drugs

2

Description
In intervention group, 50000 IU pearl of vitamin D placebo administered weekly for six weeks. The serum levels of vitamin D are evaluated at baseline and after eight weeks. The ADHD development is assessed by pediatrics psychologist at baseline and after eight weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheykhoraeis clinic
Full name of responsible person
Street address
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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Saba Ghaffary

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International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street,Tabriz , Iran

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Drug Applied Research Center, Tabriz University of Medical Sciences

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
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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