

# 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

###### Name

Saba Ghaffary

###### Name of organization / entity

Faculty of Pharmacy, Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

ghaffarys@tbzmed.ac.ir

##### 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

Sheykhoraais clinic

##### Full name of responsible person

##### Street address

##### City

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

**Street address**

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**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor of Clinical Pharmacy

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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*