

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Effect of magnesium supplements as complementary treatment with methylphenidate in children with attention-deficit/hyperactivity disorder

#### Protocol summary

##### Summary

The main objective of this experimental clinical double blind study (for doctor and patients) is to investigate the effect of magnesium as well as methylphenidate supplements on the improvement of Conners questionnaire, hyperactivity, inattention and impulsivity in two groups and then comparison between them. 7-12 age children with ADHD disorders were chosen randomly considering the inclusion criteria including IQ greater than 70, without any psychology disorder and no intake of magnesium at the last two months as well as exclusion criteria such as cutting the intake of the drug, acute physical disease and dispensing of the contribution. They were divided into two 20-membered groups, A and B. Group A would take 0.5 to 1 mg/kg/day methylphenidate tablet with 10 mg/daily magnesium tablets for 8 weeks while the other group (B) would take 0.5 to 1 mg/kg/day methylphenidate tablet with placebo. Parents Conners questionnaire would be filled for all children before and at the end of the study. Changes in score of Conners' Parent Questionnaire is as primary variable of study and side effect is as secondary variable of present study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062518927N4**

Registration date: **2017-09-30, 1396/07/08**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-09-30, 1396/07/08

##### Registrant information

##### Name

Seyed Gholamreza Noorazar

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3382 6512

##### Email address

noorazars@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences.

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2017-10-07, 1396/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of magnesium supplements as complementary treatment with methylphenidate in children with attention-deficit/hyperactivity disorder

##### Public title

Magnesium supplements treatment with methylphenidate in children with attention-deficit/hyperactivity disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: children between 7-12 aged; ADHD diagnosis by expert pediatric psychology physician using

DSM diagnosis index; No prevention for Magnesium supplements; IQ index above 70; Without other psychology disorders; No intake of Magnesium supplements since 2 months ago; Intake of methylphenidate tablet with a dose of 0.5-1 mg/kg/day as a medical treatment. Exclusion criteria: Stop the treatment by the child or parents; incorrect intake of the drug by the child; change the treatment method; Stop the treatment due to the side effects of the drug; Acute physical disease.

**Age**

From **7 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**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**

Ethics Committee of Tabriz University of Medical Sciences.

**Street address**

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Eastern Azerbaijan, Iran.

**City**

Tabriz

**Postal code****Approval date**

2015-11-09, 1394/08/18

**Ethics committee reference number**

TBZMED.REC.1394.691

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

Attention deficit hyperactivity disorder (ADHD)

**ICD-10 code**

F90.0

**ICD-10 code description**

Disturbance of activity and attention

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

Change in score of Conners' Parent Questionnaire

**Timepoint**

Beginig of study and 8 weeks later

**Method of measurement**

Conners' Parent Questionnaire

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

Adverse effects

**Timepoint**

8 weeks later

**Method of measurement**

Patient follow up

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

In intervention group: Patients will receive 0.5 to 1 mg/kg/day methylphenidate tablet with 10 mg/daily magnesium tablets for 8 weeks.

**Category**

Treatment - Drugs

**2****Description**

In control group: Patients will receive 0.5 to 1 mg/kg/day methylphenidate tablet with placebo for 8 weeks.

**Category**

Treatment - Drugs

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

Bozorgmehr Child and Adolescent Psychiatric Clinic

**Full name of responsible person**

Seyed Gholamreza Noorazar

**Street address**

Bozorgmehr Child and Adolescent Psychiatric Clinic of Tabriz University of Medical Sciences, Southern Artesh Street, Tabriz, Eastern Azerbaijan, Iran.

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences.

**Full name of responsible person**

Dr Hasan Soleimanpour

**Street address**

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, 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**

Dr. Seyed Gholamreza Noorazar

**Position**

Subspecialty of Child and Adolescent Psychiatrist.

**Other areas of specialty/work****Street address**

Faculty of Medicine, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

**City**

Tabriz

**Postal code****Phone**

+98 41 3380 3353

**Fax****Email**

noorazars@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences.

**Full name of responsible person**

Dr. Seyed Gholamreza Noorazar

**Position**

Subspecialty of Child and Adolescent Psychiatrist.

**Other areas of specialty/work****Street address**

Faculty of Medicine, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

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## Person responsible for updating data

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences.

**Full name of responsible person**

Dr. Seyed Gholamreza Noorazar

**Position**

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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*