

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Evaluating effect of the zinc as a supplement to methylphenidate in children suffering ADHD

#### Protocol summary

##### Summary

In current randomized double blinded clinical trial study on children suffering ADHD patients enrolled according to the inclusion and exclusion criteria. 60 patients aged between 7 to 12 years old with ADHD diagnosis due to DSM-IV criteria referred to subspecialty psychiatry center selected and 30 patients assigned randomly to each A and B groups. At first, demographic data and personal information form filled during and interview with parents of all participants. Children in group A received received daily methylphenidate and placebo and group B received daily methylphenidate with zinc sulfate syrup. All patients underwent treatment for 6 weeks and for all participants prior to intervention and after intervention Kanerz parents and teachers questionnaire filled after providing necessary information and final scores recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016050716077N5**

Registration date: **2016-05-22, 1395/03/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-22, 1395/03/02

##### Registrant information

##### Name

Ali Ramouz

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3441 3895

##### Email address

ali.ramouz@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Consular of research affairs, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-04-04, 1392/01/15

##### Expected recruitment end date

2014-04-04, 1393/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating effect of the zinc as a supplement to methylphenidate in children suffering ADHD

##### Public title

Zinc supplement effect in treatment of the children with attention deficiency-hyperactivity disorder (ADHD)

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: children aged between 7 to 12 years; ADHD diagnosis made by youth and children psychiatry subspecialist according to DSM-IV criteria and approved by K-SADS form; no prohibition to consumption of the zinc supplements such as copper consumption; IQ more than 70; without any other psychiatric disorders approved by K-SADS form; no history of zinc consumption during last two months; receiving methylphenidate tablet in 0.5 to 1 mg/kg/day doses as treatment Exclusion criteria: cancelling participation by

parents or child consciously; not consuming according to the prescription; change in treatment method; interrupting treatment due to any reason such as drug adverse effects

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### 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 Committe of Tabriz University of Medical Sciences

##### Street address

Research and technology department- Daneshgah Street- Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2016-01-18, 1394/10/28

#### Ethics committee reference number

TBZMED.REC.1394.1131

## Health conditions studied

### 1

#### Description of health condition studied

Attention deficiency-hyperactivity disorder

#### ICD-10 code

F90.0

#### ICD-10 code description

Disturbance of activity and attention

## Primary outcomes

### 1

#### Description

Determining symptoms severity improvement in each group according to the Kanerz questionnaire scores

#### Timepoint

After intervention

#### Method of measurement

Using Kanerz parents and teachers questionnaire

## Secondary outcomes

### 1

#### Description

Determining zinc supplement effect on hyperactivity score improvement in Kanerz questionnaire

#### Timepoint

Before intervention, after intervention

#### Method of measurement

Using Kanerz parents and teachers questionnaire

### 2

#### Description

Determining zinc supplement effect on inattention score improvement in Kanerz questionnaire

#### Timepoint

Before intervention, after intervention

#### Method of measurement

Using Kanerz parents and teachers questionnaire

### 3

#### Description

Determining zinc supplement effect on hyperactivity score impulsivity in Kanerz questionnaire

#### Timepoint

Before intervention, after intervention

#### Method of measurement

Using Kanerz parents and teachers questionnaire

## Intervention groups

### 1

#### Description

Group B: Methylphenidate tablet in 0.5 to 1 mg/kg/day doses accompanied by 10 milliliter zinc sulfate syrup for 6 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Group A: Methylphenidate tablet in 0.5 to 1 mg/kg/day doses accompanied with placebo for 6 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Children and youth psychiatry subspecialty clinic

**Full name of responsible person****Street address****City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Gholamreza Nour azar

**Street address**

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 of 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 Nour Azar

**Position**

Assistant professor of children and youth psychiatry

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

Razi Hospital, Golshahr Street

**City**

Tabriz

**Postal code****Phone**

+98 41 3334 1705

**Fax****Email**

Noorazars@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Science

**Full name of responsible person**

Dr. Seyed Gholamreza Nour azar

**Position**

Children and youth subspecialist

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

Razi hospital, Golshahr street

**City**

Tabriz

**Postal code****Phone**

+98 41 3334 1705

**Fax****Email**

Noorazars@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Ramouz

**Position**

Medical Student

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

Imam Reza hospital, Daneshgah street

**City**

Tabriz

**Postal code****Phone**

+98 41 3441 3895

**Fax****Email**

ali.ramouz@gmail.com

**Web page address**

## 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*