

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Investigating the effectiveness of methylphenidate and combination of magnesium and zinc and calcium in treatment of symptoms of attention deficit hyperactivity disorder (ADHD) among 6 to 12 children suffered from ADHD in Zahedan city

#### Protocol summary

##### Summary

(1) Objectives: Investigate the effect of pharmaceutical composition of methylphenidate as well as a combination of magnesium and zinc and calcium for the treatment of attention deficit hyperactivity disorder (ADHD) (2) Design: Randomized, Double blind, Placebo controlled, Single center, Phase 2 clinical trial (3) Setting and conduct: After selecting the patients and achieving their parent's consent, the method and the purpose of this study were explained to them. Then, a demographic information form was completed for each child separately. Patients were randomly divided into two groups using a table of random numbers (4) Participants including major eligibility criteria: Inclusion criteria: Aged 6 to 12 years; diagnosis of attention deficit hyperactivity disorder (ADHD) based on DSM-IV-TR diagnostic criteria Exclusion criteria: Any simultaneous major psychiatric disease, except confrontational behavior and learning disorder Target sample size: 40 (5) Intervention: In the intervention group: Methylphenidate tablets orally used with a starting dose of 0.3 mg/kg, twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and tablets containing 133 mg magnesium and 5 mg zinc and 333 mg calcium, one daily for 8 weeks In the control group: Methylphenidate tablets were used orally with a starting dose of 0.3 mg/kg twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and received placebo pills, once each day for 8 weeks (6) Main outcome measures (variables): Medication, Side effects, Disorder severity

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015092624209N1**

Registration date: **2016-04-24, 1395/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-24, 1395/02/05

##### Registrant information

###### Name

Mahboubeh Firoozkouhi Moghadam

###### Name of organization / entity

Zahedan University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5796

###### Email address

m.firoozkoohi@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research and Technology at Zahedan University of Medical Sciences and Health Services

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-02-20, 1393/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating the effectiveness of methylphenidate and combination of magnesium and zinc and calcium in treatment of symptoms of attention deficit hyperactivity disorder (ADHD) among 6 to 12 children suffered from ADHD in Zahedan city

## Public title

Investigating the effectiveness of methylphenidate and combination of magnesium and zinc and calcium in treatment of patients with attention deficit hyperactivity disorder (ADHD) in Zahedan City

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Aged 6 to 12 years; diagnosis of attention deficit hyperactivity disorder (ADHD) based on DSM-IV-TR diagnostic criteria; the scale to measure attention deficit hyperactivity disorder (ADHD) in parent and teacher form, at least 20. Exclusion criteria: Any simultaneous major psychiatric disease, except confrontational behavior and learning disorder; IQ less than 70; the use of psychotropic drugs or narcotic materials in the past two weeks; any important neurological diseases; taking any drug affecting the nervous system, at least two weeks prior to the study.

## Age

From **82 years** old to **88 years** old

## Gender

Both

## Phase

2

## 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

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences and Health Services

##### Street address

Pardis office complex at Zahedan University of Medical Sciences and Health Services, Persian Gulf Boulevard, Dr. Hessabi square, Zahedan, Iran

##### City

Zahedan

##### Postal code

98167-43463

#### Approval date

2014-11-23, 1393/09/02

#### Ethics committee reference number

6753

## 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

Medication

#### Timepoint

Before intervention and 2, 4, 6 and 8 weeks after intervention

#### Method of measurement

Attention deficit hyperactivity disorder (ADHD) Rating Scale

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

Before intervention and 2, 4, 6 and 8 weeks after intervention

#### Method of measurement

Attention deficit hyperactivity disorder (ADHD) Rating Scale

### 2

#### Description

Disorder severity

#### Timepoint

Before intervention and 2, 4, 6 and 8 weeks after

intervention

### Method of measurement

Attention deficit hyperactivity disorder (ADHD) Rating Scale

## Intervention groups

### 1

#### Description

In the intervention group: Methylphenidate tablets orally used with a starting dose of 0.3 mg/kg, twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and tablets containing 133 mg magnesium and 5 mg zinc and 333 mg calcium, one daily for 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

In the control group: Methylphenidate tablets were used orally with a starting dose of 0.3 mg/kg twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and received placebo pills, once each day for 8 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baharan Educational, Clinical and Research Psychiatry Center

##### Full name of responsible person

Dr. Mahboubeh Firoozkouhi Moghadam

##### Street address

In front of the Grain office, Imam Khomeini street, Zahedan

##### City

Zahedan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research and Technology at Zahedan University of Medical Sciences and Health Ser

##### Full name of responsible person

Dr. Houshang Rafighdoust

##### Street address

Pardis office complex at Zahedan University of Medical Sciences and Health Services, Persian Gulf Boulevard, Dr. Hessabi square, Zahedan, Iran

##### City

Zahedan

#### Grant name

125401

#### Grant code / Reference number

10506

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

Yes

#### Title of funding source

Vice Chancellor for Research and Technology at Zahedan University of Medical Sciences and Health Ser

#### 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

Vice Chancellor for Research and Technology at Zahedan University of Medical Sciences and Health Ser

##### Full name of responsible person

Dr. Houshang Rafighdoust

##### Position

Professor of Anatomy

##### Other areas of specialty/work

##### Street address

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98167-43463

##### Phone

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<http://highmail.zaums.ac.ir>

##### Web page address

[www.zaums.ac.ir](http://www.zaums.ac.ir)

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Vice Chancellor for Research and Technology at Zahedan University of Medical Sciences and Health Ser

##### Full name of responsible person

Dr. Mahboubeh Firoozkouhi Moghadam

**Position**

University Assistant Professor

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

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Vice Chancellor for Research and Technology at  
Zahedan University of Medical Sciences and Health  
Ser

**Full name of responsible person**

Dr. Mahboubeh Firoozkouhi Moghadam

**Position**

University Assistant Professor

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

Pardis office complex at Zahedan University of  
Medical Sciences and health services, Persian Gulf  
Boulevard, Dr. Hessabi square, Zahedan, Iran

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**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*