Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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

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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
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Person responsible for updating data

Contact
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Full name of responsible person
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University Assistant Professor
Other areas of specialty/work
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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