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

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Ali Ramouz
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Iran (Islamic Republic of)
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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 Mecial 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
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Person responsible for updating data

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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