Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Effect of Zinc plus Multivitamin in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) Treated with Methylphenidate

Protocol summary

Study aim
Evaluation of Effect of Zinc plus Multivitamin in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) Treated with Methylphenidate
Design
Controlled clinical trial of random intervention
Settings and conduct
Patients with Attention Deficient Hyperactivity Disorder refer to Razi Hospital
Participants/Inclusion and exclusion criteria
Patients aged 6 to 12 years old will involve after diagnosis of ADHD according to DSM-V
Intervention groups
The intervention group receives zinc plus multivitamin and methylphenidate, and the control group receives only methylphenidate for 3 months.
Main outcome variables
Appetite; Body Mass Index; Severity of symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150706023083N4**
Registration date: **2020-05-03, 1399/02/14**
Registration timing: **prospective**

Last update: **2020-05-03, 1399/02/14**
Update count: **0**
Registration date
2020-05-03, 1399/02/14

Registrant information
Name
Haleh Rezaee
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 3337 2250
Email address
rezaeeha@tbzmed.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-21, 1399/03/01
Expected recruitment end date
2021-05-22, 1400/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Effect of Zinc plus Multivitamin in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) Treated with Methylphenidate

Public title
Effect of Zinc plus Multivitamin in Attention Deficit Hyperactivity Disorder
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of ADHD meeting criteria according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition Stable treatment with methylphenidate Not receiving supplement before this study Age range 6-12 years old Zinc deficiency

Exclusion criteria:
Receiving supplement before this study Other psychiatric disease like autism, Chronic disease, Taking anticonvulsant Inability to understand and sign consent

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization does by using randomized block

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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 Science

Street address
No.20, Safa St., Besaat Ave., Mirdamad

City
Tabriz

Province
East Azarbaijan

Postal code
5166956547

Approval date
2020-02-04, 1398/11/15

Ethics committee reference number
IR.TBZMED.REC.1398.1180

Health conditions studied

1

Description of health condition studied
Attention Deficient Hyperactivity Disorder

ICD-10 code
F90.9

ICD-10 code description
Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description
Appetite

Timepoint
On arrival and after 2, 4, 6, 8, 12 weeks after receiving supplement

Method of measurement
Prepared appetite questionnaire

2

Description
Weight changes

Timepoint
On arrival and after 2, 4, 6, 8, 12 weeks after receiving supplement

Method of measurement
Scale

3

Description
Body Mass Index

Timepoint
On arrival and after 2, 4, 6, 8, 12 weeks after receiving supplement

Method of measurement
The body mass divided by the square of the body height

Secondary outcomes

1

Description
severity of ADHD symptoms

Timepoint
On arrival and after 2, 4, 6, 8, 12 weeks after receiving supplement

Method of measurement
Parents conners questionnaire

Intervention groups

1

Description
Intervention group: This group receives zinc plus multivitamin and methylphenidate for 3 months

Category
Treatment - Drugs

2

Description
Control group: This group receives only methylphenidate for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Outpatient Clinic of Razi Hospital

Full name of responsible person
Dr Seyed Gholamreza Noorazar

Street address
Sheykh Mohammad Khiyabani Ave., Bakeri Blvd., Elgoli, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Haleh Rezaee

Street address
Faculty of Pharmacy, 6th floor, Department of Clinical Pharmacy, University Street, Tabriz

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Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Haleh Rezaee

Position
Assistant Professor of Clinical Pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There isn't more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available