

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 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 committee 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

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
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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