

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Folic acid in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) Treated with Methylphenidate

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of effect of Folic acid in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) Treated with Methylphenidate

Last update: **2020-11-14, 1399/08/24**

Update count: **0**

Registration date

2020-11-14, 1399/08/24

Design

clinical trial with control group, with parallel groups, not blind, randomized, phase 3, on 100 patients. Accidental block randomization

Registrant information

Name

Haleh Rezaee

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Settings and conduct

Patients with Attention Deficient Hyperactivity Disorder refer to Razi Hospital. This clinical trial involved 100 patients with ADHD aged 6 to 12. Patients were randomly (Accidental block randomization) divided in to two groups: A case group which received MPH (0.5 - 1 mg) and folic acid supplement; and a control group which received MPH (0.5 - 1 mg) for 12 weeks. Assessments, comprising the appetite questionnaire, anthropometric measurements and conners parent questionnaire, were conducted by a psychiatric at baseline and then at 2, 4, 6, 8 and 12 weeks after the medication was started using repeated measure analysis.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Patients aged 6 to 12 years old will be involved after diagnosis of ADHD according to DMS-V

Expected recruitment start date

2020-11-02, 1399/08/12

Expected recruitment end date

2021-11-03, 1400/08/12

Intervention groups

The intervention group receives folic acid and methylphenidate, and the control group receives only methylphenidate for 3 months.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Appetite; Body Mass Index; severity of symptoms

Trial completion date

empty

General information

Scientific title

Effect of Folic acid in Children and Adolescents with Attention Deficit Hyperactivity Disorder (ADHD) Treated with Methylphenidate

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023083N6**

Registration date: **2020-11-14, 1399/08/24**

Public title

Effect of folic acid 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
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 will be done using block of size 4. a randomized block procedure would be as follows: a block size of 4 is chosen, possible balanced combinations with 2 C (control) and 2 T (treatment) subjects are calculated, and blocks are randomly chosen to determine the participants' assignment into the groups.

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

کمیته اخلاق دانشگاه علوم پزشکی تبریز

Street address

میرداماد، خیابان بعثت، کوچه ی صفا، پلاک 20

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Postal code

5166956547

Approval date

2020-10-05, 1399/07/14
Ethics committee reference number
IR.TBZMED.REC.1399.685

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 Folic acid (1mg/day) and methylphenidate (0.5-1 mg/kg) two to three times a day for 3 months. Methylphenidate is preferably Ritalin10 brand (manufactured by Novartis Company) and in the absence of Ritalin, Rubifen10 (manufactured by Rubio company) is used.

Category

Treatment - Drugs

2

Description

Control group: This group receives only methylphenidate (0.5-1 mg/kg) for 3 months. Methylphenidate is preferably Ritalin brand (manufactured by Novartis Company) and in the absence of Ritalin, Rubifen (manufactured by Rubio company) is used.

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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librazi@tbzmed.ac.ir

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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Full name of responsible person

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Person responsible for updating data**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

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