

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A survey of effect of iron supplementation(ferrous sulfate) versus placebo on attention-deficit/hyperactivity disorder symptoms in children under Methylphenidate treatment

Protocol summary

Summary

This double blinded randomized clinical trial study, with control and parallel groups, will be done on 50 patients with attention-deficit/hyperactivity disorder during 12 weeks. Diagnosis is based on clinical criteria of DSM-IV TR. Three ml of blood sample from children will be taken after obtaining parent informed written contest, and those patients who do not have anemia and their blood ferritin level are lower than 30 ng/ml, will be included in study. Children randomly will be divided into two groups of 25 patients, after screening. Responsiveness to methylphenidate medication will be evaluated and compared by Conners' parent questionnaire in two groups after 12 weeks usage of iron supplementation (ferrous sulfate 80 mg tablets) and placebo. Conners' questionnaire will be filled by parent in first, sixth, and twelfth weeks and severity of symptoms will be analyzed and compared with statistical tests in two groups of iron supplementation and placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212012269N2**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

Name

Elham Bidabadi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey of effect of iron supplementation(ferrous sulfate) versus placebo on attention-deficit/hyperactivity disorder symptoms in children under Methylphenidate treatment

Public title

Effect of ferrous sulfate on attention-deficit/hyperactivity disorder symptoms in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Children with attention-deficit/hyperactivity disorder based on DSM-IV TR and under Methylphenidate treatment 2. Lack of anemia

(Hemoglobin lower than 11 g/dl) 3. Blood ferritin level lower than 30 ng/ml Exclusion criteria: 1. Comorbidity of attention-deficit/hyperactivity disorder with other psychiatric disorders 2. Serious and chronic medical disorders (such as malnutrition) 3. Mental retardation 4. Recent inflammation or infection 5. Use of psychopharmacological medications 6. Iron supplementation consumption during recent 3 months, or contraindication for use it. 7. Severe fever (because of pseudo increase in ferritin level) 8. Hypothyroidism (because of pseudo decrease in ferritin level)

Age

From **4 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Type of randomization: Blocked randomization The study medications (Ferrous sulfate and placebo tablets) will be indistinguishable in terms of appearance, weight and taste. The investigators together with the participants (children and their parents) will be blinded to the randomization lists until the end of the trial. "Double blind" will be used as a stringent way of study, to eliminate of unrecognized biases, and to achieve a higher scientific standard than "blind" or "non-blind" experiments.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Vice chancellor for research, Guilan University of Medical Sciences, West Shahid Beheshti Blvd.

City

Rasht

Postal code

4193893345

Approval date

2012-10-23, 1391/08/02

Ethics committee reference number

1910231203

Health conditions studied

1

Description of health condition studied

Attention deficit/hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

A group of disorders characterized by an early onset (usually in the first five years of life), lack of persistence in activities that require cognitive involvement, and a tendency to move from one activity to another without completing any one, together

Primary outcomes

1

Description

Ferritin

Timepoint

Before intervention, 3 months later

Method of measurement

Blood sampling, monobind kit, ELISA method

2

Description

Hemoglobin

Timepoint

Before intervention, 3 months later

Method of measurement

Blood sampling, immunometric method with autoanalyzer

3

Description

TIBC

Timepoint

Before intervention, 3 months later

Method of measurement

Blood sampling, Ziest Chem kit, fluorometry method

4

Description

Iron

Timepoint

Before intervention, 3 months later

Method of measurement

Blood sampling, Ziest Chem kit, fluorometry method

Secondary outcomes

1

Description

Attention Deficit Hyperactivity Disorder (ADHD) index

Timepoint

First, Sixth, and twelfth weeks

Method of measurement

Conners' Parent Rating Scale (CPRS)

Intervention groups

1

Description

Ferrous sulfate (brand name: Ferrous sulfate), 80 mg oral tablet, manufactured by Shahre Daru Co., daily for 3 months

Category

Treatment - Drugs

2

Description

Placebo, oral tablet, manufactured by Shahre Daru Co., contains: Lactose- Avicel- Polyvinylpyrrolidone (PVP), daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa educational & remedial center (child psychology clinic)

Full name of responsible person

Maryam Kousha, MD. (child psychologist)

Street address

Shahid Beheshti Blvd., 15th Khordad St., Heshmat Sq.

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasoul Sobhani

Street address

West Shahid Beheshti Blvd., Gas Sq., No. 477

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Rasht

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, Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Hamed Esmaili Gurabi

Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Pediatric Neurologist

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