

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy and safety of ferrous sulphate add-on standard treatment regimen for children with attention-deficit hyperactivity disorder in 7- to 14 year-Old without iron deficiency and anemia : A 12 weeks randomized, open-label, parallel group Study

Protocol summary

Study aim

Evaluation of the efficacy and safety of ferrous sulphate add-on standard treatment regimen for children with attention-deficit hyperactivity disorder(ADHD) and without iron deficiency and anemia in 7- to 14 year-Old On the ADHD symptoms and growth status

Design

A randomized, open-label, controlled clinical trial, design of 38 patients with ADHD(1: 1 in each group), between March and October 2017

Settings and conduct

Pediatric Psychiatric Clinic of Zare Hospital affiliated to Mazandaran University of Medical Sciences, Sari, Iran
Pediatric Psychiatric Clinic of Roozbeh hospital affiliated to Tehran University of Medical Sciences, Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: 7-14 years old children with ADHD and without iron deficiency and anemia
Exclusion criteria: acute phase of the disease; underlying disease; mental retardation; Previous treatment with any enriched products with iron at least 2 months before the initiation

Intervention groups

Subjects in the intervention group receive ferrous sulphate tablet with a dose of 1 mg / kg according to elemental iron with standard therapeutic regimen and the control group receive standard therapeutic regimen alone for 12 weeks

Main outcome variables

Strengths and Difficulties Questionnaire for assessment of emotional and behavioral problems; Rutter and Conners' Parent Rating Scale for assessment of the improvement of the ADHD symptoms were used at the baseline and on the 45th and 90th days. Serum iron; ferritin; Hemoglobin ; Hematocrit; Total iron-binding capacity (TIBC) ; Height; weight; waist; body mass index; serum cholesterol profiles; fasting blood sugar were

measured at the baseline and on the 90th day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120314009297N3**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **retrospective**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

Registration date

2018-04-30, 1397/02/10

Registrant information

Name

narjes hendouei

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 911 327 0107

Email address

hendoieen@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2017-03-21, 1396/01/01
Actual recruitment end date
2017-10-23, 1396/08/01
Trial completion date
empty

Scientific title

Efficacy and safety of ferrous sulphate add-on standard treatment regimen for children with attention-deficit hyperactivity disorder in 7- to 14 year-Old without iron deficiency and anemia : A 12 weeks randomized, open-label, parallel group Study

Public title

The effect of ferrous sulphate on the treatment of symptoms in children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

7-14 years old children Diagnosed attention deficit hyperactivity disorder children by two psychiatrists and based on DSM-V and without iron deficiency and anemia (Serum ferritin above 15 µg /L and serum hemoglobin equal to or greater than 11 g /dl) All patients are on standard treatment regimen for attention-deficit hyperactivity disorder for at least 3 months and a stable dose for at least 1 month.

Exclusion criteria:

Acute phase of the disease Psychiatric comorbidity as defined by DSM-V (bipolar disorder, Major depressive disorder) Mental retardation Neurological diseases such as delirium, seizure, traumatic brain injury Current significant unstable medical illness (such as unstable cardiac disease, hepatic or renal impairment, evidence or history of malignancy or any significant hematological, endocrine)/ HIV infection / abnormalities on physical examination, vital signs, electrocardiogram (ECG), or clinical laboratory values Hypersensitivity to iron sulphate Previous treatment with any enriched medical products with iron at least 2 months before the initiation Unwillingness of the patient or his guardian to participate in the study

Age

From **7 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **38**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random numbers and 1: 1 ratio in treatment group and control group

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 Mazandaran University of Medical Sciences

Street address

Moallem street, Moallem square, Vice chancellor for research

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2017-06-06, 1396/03/16

Ethics committee reference number

IR.MAZUMS.REC.1396.2832

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description

Emotional and behavioral problems

Timepoint

At the baseline and on the 45th and 90th days

Method of measurement

Strengths and Difficulties Questionnaire (SDQ)

2

Description

Severity of symptoms in hyperactivity, impulsivity and cognitive impairment in children with ADHD

Timepoint

At the baseline and on the 45th and 90th days

Method of measurement

Rutter Behavioral Disorder Questionnaire

3

Description

Severity of symptoms in hyperactivity, impulsivity and cognitive impairment in children with ADHD

Timepoint

At the baseline and on the 45th and 90th days

Method of measurement

Conners' Parent Rating Scale

4

Description

Serum iron level

Timepoint

At the baseline and on the 90th day

Method of measurement

ELISA Kit

5

Description

Serum ferritin level

Timepoint

At the baseline and on the 90th day

Method of measurement

ELISA Kit

6

Description

Hemoglobin; Hematocrit

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory data

7

Description

Total iron-binding capacity (TIBC)

Timepoint

At the baseline and on the 90th day

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Height

Timepoint

At the baseline and on the 90th day

Method of measurement

Height gauge

2

Description

Weight

Timepoint

At the baseline and on the 90th day

Method of measurement

Scales

3

Description

Waist circumference

Timepoint

At the baseline and on the 90th day

Method of measurement

Tape

4

Description

Body mass index

Timepoint

At the baseline and on the 90th day

Method of measurement

Using the formula kilograms per square meter of height(Kg/m²)

5

Description

Serum total cholesterol level

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

6

Description

Low-density lipoprotein(LDL)

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

7

Description

High density lipoprotein (HDL)

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

8

Description

Serum triglyceride level

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

9

Description

Fasting blood sugar

Timepoint

At the baseline and on the 90th day

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: receive ferrous sulphate tablet with a dose of 1 mg / kg according to elemental iron for 12 weeks along with their standard therapeutic regimen

Category

Treatment - Drugs

2

Description

Control group: receive their standard therapeutic regimen alone for 12 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Psychiatric Clinic of Zare Hospital

Full name of responsible person

Narjes Hendouei

Street address

Zare Hospital, Taravat St., Neka Road

City

Sari

Province

Mazandaran

Postal code

33971-48157

Phone

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Email

hendoieen@yahoo.com

2

Recruitment center

Name of recruitment center

Pediatric Psychiatric Clinic of Roozbeh hospital

Full name of responsible person

Samaneh Farnia

Street address

Roozbeh hospital, District 11, Karegar St, No. 606

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sm.farnia@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Moallem street, Moallem square-Vice chancellor for research

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tmaae@liv.ac.uk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Narjes Hendouei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

I have not decided yet - its release plan is still unclear

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable