Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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
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2

Recruitment center
Name of recruitment center
Pediatric Psychiatric Clinic of Roozbeh hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati
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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
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Medical Pharmacy
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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