Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of standard Iron replacement therapy on ECG parameters in 9-18 years old adolescents

Protocol summary

Study aim
Recognition of effect of iron replacement therapy on reversibility of arrhythmogenic ECG parameters and as result more attention to treatment of iron deficiency for preventing of complications such as arrhythmia, syncope and sudden cardiac death.

Design
Ferritin deficient patients will be treated by elemental iron(5 mg/kg) and the ECG parameters including P wave duration,QTc and Twave peak to end distance will be evaluated before and after treatment.There is no control group.

Settings and conduct
9-18 years old persons came to health centers of Birjand city with low serum ferritin will be evaluated by history and physical examination and standard 12 lead ECG will be taken.

Participants/Inclusion and exclusion criteria
9-18 years old adolescents living in Birjand with serum ferritin below 15 mg/dl

Intervention groups
In this group,iron deficient patients will be treated by supplement iron tablets(dose:3-5 mg/kg).and ECG parameters before and after therapy will be compared.

Main outcome variables
Arrhythmogenic ECG parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190114042357N1**
Registration date: **2019-03-13, 1397/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-13, 1397/12/22**
Update count: **0**

Registration date
2019-03-13, 1397/12/22

Registrant information

Name
Vahid Shahriari

Name of organization / entity

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Iran (Islamic Republic of)

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+98 56 3239 5000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-30, 1397/11/10

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of standard Iron replacement therapy on ECG parameters in 9-18 years old adolescents

Public title
Comparison of ECG parameters before and after iron replacement therapy in iron deficient adolescents.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Parental concest Patient cooperation for taking history, physical examination,ECG and blood sampling Absence

of inflammatory disease during three weeks according to history and physical examination. Absence of chronic renal disease Absence of rheumatologic,collagen vascular or other chronic disease Absence of any cardiac disease including congenital or inflammatory. Absence of any drug consumption in three recent weeks because of any probable effect on ECG parameters

Exclusion criteria:

Acute inflammatory disease Hypothyroidism

Age

From **9 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand university of medical sciences

Street address

Ghafari Blvd.

City

Birjand

Province

South Khorasan

Postal code

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Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.BUMS.REC.1397.073

Health conditions studied

1

Description of health condition studied

Iron deficiency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum ferritin level

Timepoint

QTc distance measurement

Method of measurement

Ferritin measurment by electrochemiluminescence method by Cobas Japan and Roche kit Germany.

Secondary outcomes

1

Description

Serum ferritin level

Timepoint

QTc distance measurment

Method of measurement

Ferritin measurment by electrochemiluminescence method by Cobas Japan and Roshe kit Germany

Intervention groups

1

Description

Patients with ferritin below 15 mg/dl and their parents will be educated for treatment of iron deficiency and importance of continuing treatment.Then will be treated by iron replacement with trade name of ferrous sulfate made by Daroopakhsh company and bach number:769,including 50 milligram of elemental Iron, 3 to 5 milligram per kilogram(max dose 150 mg) for 3 months. finally they will be visited and history and physical exam will be done.Then 12 lead standard electrocardiogram and blood sample for CBC and Ferritin will be taken similar to before treatment. Ferritin must be above 15 or the patient will be excluded of research. Then electrocardiogram markers will be conferred with before treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Birjand university of medical sciences

Full name of responsible person

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Sponsors / Funding sources

1

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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
Birjand 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
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Labolatory results ECG records
When the data will become available and for how long
6 months after publication of results
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Use in systematic reviews
From where data/document is obtainable
Via e-mail address:shahriarivahiddr@bums.ac.ir
What processes are involved for a request to access data/document
Request by e-mail and sending of results about two months later
Comments