Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Electrocardiographic Changes in Pateints WithIron Deficiency Anemia and Minor Thalassemia in Ali-Asghar Hospital in Zahedan in 2025

Protocol summary

Study aim

Assessing Electrocardiographic Changes in Children with Iron Deficiency Anemia and Minor Thalassemia Before and After Treatment compared with the controls

Design

This single-blinded study evaluates ECG changes in 135 children (aged 5–18) at Ali Asghar Hospital, divided into three groups: IDA, Minor Thalassemia, and healthy controls (n=45 each). IDA participants receive 5 mg/kg/day ferrous sulfate, and Minor Thalassemia participants receive 1 mg/day folic acid, both for 3 months. ECG and hematologic parameters are assessed before and after treatment. Investigators remain blinded to group allocation during data analysis.

Settings and conduct

Sampling in this study was conducted using convenient and accessible sampling at Ali Asghar Hospital in Zahedan.

Participants/Inclusion and exclusion criteria

Inclusion criteria are children with clinical diagnoses of IDA (low hemoglobin, ferritin, serum iron, and high total iron-binding capacity) or Minor Thalassemia and healthy controls with no history of anemia, thalassemia, or chronic illnesses. Exclusion criteria include children with significant health conditions, severe anemia, receiving interfering medications, or unable to comply with study protocols.

Intervention groups

In this study, children in the Iron Deficiency Anemia (IDA) group receive ferrous sulfate at a dose of 5 mg/kg/day for 3 months. Children in the Minor Thalassemia group receive folic acid at 1 mg/day for 3 months to support red blood cell production.

Main outcome variables

Prediction and prevention of cardiac disorders in children with iron deficiency anemia and thalassemia minor.

General information

Reason for update

Acronym

EKG

IRCT registration information

IRCT registration number: **IRCT20250416065355N1**

Registration date: **2025-05-14, 1404/02/24**

Registration timing: **prospective**

Last update: **2025-05-14, 1404/02/24**

Update count: **0**

Registration date

2025-05-14, 1404/02/24

Registrant information

Name

Sahar SAFAPOUR

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

2025-05-22, 1404/03/01

Actual recruitment end date

2025-08-23, 1404/06/01

Trial completion date

2025-10-13, 1404/07/21

Scientific title
Evaluation of Electrocardiographic Changes in Pateints WithIron Deficiency Anemia and Minor Thalassemia in Ali-Asghar Hospital in Zahedan in 2025

Public title
Studying the Electrocardiographic changes in patients with Iron deficiency anemia and minor thalassemia

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 5 to 18 years. The child has minor thalassemia or iron deficiency anemia.

Exclusion criteria:
The presence of any other underlying disease. Other types of anemia Using drugs that impair iron absorption failing to adhere to regular treatment Having previous iron or anti-inflammatory treatments

Age
From **5 years** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Investigator

Sample size
Target sample size: **135**
Actual sample size reached: **135**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is conducted as a single-blinded trial, in which the investigators responsible for data collection and outcome assessment are blinded to group allocation. Although participants and those administering the interventions are aware of the treatment assignments, the investigators analyzing the data do not have access to group information during the evaluation phase. This approach minimizes potential assessment bias and helps ensure the objectivity and validity of the results.

Placebo
Not used

Assignment
Parallel

Other design features
This study is a prospective, single-blinded, controlled clinical trial designed to compare hematologic and electrocardiographic (ECG) parameters in children diagnosed with Iron Deficiency Anemia (IDA), Minor Thalassemia, and healthy Controls. A total of 135 children aged 5 to 18 years are enrolled and divided equally into three groups (n = 45 per group). Sampling is conducted using a convenient and accessible method at Ali Asghar Hospital in Zahedan. Participants are allocated to study groups based on their clinical diagnosis. The study is non-randomized; however, investigators responsible for data collection and analysis are blinded to group assignments to reduce assessment bias.Children in the IDA group receive ferrous sulfate at a dose of 5 mg/kg/day for 3 months. Those in the Minor Thalassemia group receive folic acid at a dose of 1 mg/day for 3 months. The Control group receives no pharmacological intervention. Body weight is measured monthly to adjust the dose of ferrous sulfate as needed.All participants follow a similar, age-appropriate, and healthy diet during the study. At the end of the treatment period, ECG parameters are assessed by a pediatric cardiologist who is also one of the study authors, ensuring expert and standardized evaluation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Dr. Hesabi Square - University of Medical Sciences Campus

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743111

Approval date
2020-11-22, 1399/09/02

Ethics committee reference number
IR.ZAUMS.REC.1399.373

Health conditions studied

1

Description of health condition studied
Iron deficiency anemia and thalassemia minor

ICD-10 code
D50.9

ICD-10 code description
Iron deficiency anemia, unspecified

2

Description of health condition studied
Minor thalassemia

ICD-10 code
D56.3

ICD-10 code description
Thalassemia minor

Primary outcomes

1

Description
ECG results
Timepoint
3months
Method of measurement
ECG measurements (PWd, QTd, QTcd, Tp-e interval, Tp-e dispersion)

2

Description
Hemoglobin level
Timepoint
3months
Method of measurement
compelet blood count

3

Description
ferritin
Timepoint
3months
Method of measurement
Serum Iron

Secondary outcomes

empty

Intervention groups

1

Description
In Intervention Group 1, children aged 5 to 18 years with iron deficiency anemia were treated with ferrous sulfate. The medication was administered at a daily dose of 5 mg of elemental iron per kilogram of body weight for a duration of 3 months and was given after meals due to potential gastrointestinal side effects.
Category
Treatment - Drugs

2

Description
In Intervention Group 2, children aged 5 to 18 years with minor thalassemia were treated with folic acid. The medication was administered at a daily dose of 1 mg for a duration of 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Asghar Hospital, Zahedan
Full name of responsible person
Ṡahar safapour moghadam
Street address
Azadi Street, Ali Asghar Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Zahedan University of Medical Sciences
Proportion provided by this source
10
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
Zahedan University of Medical Sciences

Full name of responsible person
Noor Mohammad Noori

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Electrocardiography changes

When the data will become available and for how long
Access begins 6 months after results are published.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
There are no other conditions

From where data/document is obtainable
Referral to the research department of Imam Ali Hospital, Zahedan

What processes are involved for a request to access data/document
The request will be sent to the research department of Imam Ali Hospital after the documents have been confirmed.

Comments
This study represents the first of its kind to compare the effects of two different therapeutic interventions—iron supplementation for children with Iron Deficiency Anemia (IDA) and folic acid supplementation for those with Minor Thalassemia—within a structured clinical framework.

Furthermore, it incorporates a healthy control group to serve as a baseline reference, allowing for a comprehensive evaluation of changes in electrocardiographic (ECG) and hematological parameters across all groups. By comparing the pre- and post-treatment outcomes in the intervention groups with those of the healthy controls, this study aims to generate robust evidence on the specific impacts of therapies in pediatric patients with IDA and Minor Thalassemia. The inclusion of a healthy control group enhances the validity of the findings, providing a normative benchmark against which intervention efficacy can be assessed. This design allows for a clearer understanding of how each condition uniquely responds to treatment relative to a baseline of normal pediatric health.