Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

The effect of iron supplementation during menstrual bleeding on bleeding and hemoglobin level in students: A Randomized Clinical Trial

Protocol summary

Study aim
Determining the effect of iron supplementation during menstrual bleeding on bleeding volume and hemoglobin level

Design
Clinical trial with control group, with parallel groups, 3-way blind, randomized, phase 3 on 160 people, cards or envelope shuffing function is used for randomization

Settings and conduct
Sampling will be done in Rafsanjan University of Medical Sciences. The iron pills and placebo will be packed with the codes 1 and 2. Samples, researcher and the analyzer will be unaware of the type of drug. The hemoglobin level is checked before the intervention and if samples are anemic they are removed. The duration of the study is 4 menstrual cycles. The first cycle is with no intervention, during which the samples record the amount of menstrual bleeding in the Higham chart. Iron pills and Plus Bo are given to samples to take 3 menstrual cycles. The first group takes iron pills in the first 4 days of menstrual bleeding 1 a day and the second group takes Plus Bo in the same way. Each cycle they fill the Higham chart. A week after taking the last iron or Plus Bo pill, hemoglobin level is measured again

Participants/Inclusion and exclusion criteria
Lack of vitamin intake and iron pills in the last 3 months/Lack of pregnancy and lactation/Lack of endocrine disorders like diabetes and thyroid problems/Hemoglobin greater than or equal to 12 grams per deciliter

Intervention groups
The intervention group takes ferrous sulfate pills containing 50 mg of iron ions in the first 4 days of menstrual bleeding and the control group receives Plus Bo in the first 4 days of menstrual bleeding.

Main outcome variables
There is no difference in the amount of menstrual bleeding in the intervention and control groups before the intervention and after each intervention. There is no difference in the amount of hemoglobin in the intervention and control groups before the intervention and after intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160308026971N11**
Registration date: **2020-12-20, 1399/09/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-20, 1399/09/30**
Update count: **0**

Registration date
2020-12-20, 1399/09/30

Registrant information

Name
Marzeyeh Loripoor

Name of organization / entity
Rafsanjan University Medical Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-04, 1399/08/14

Expected recruitment end date
2021-03-04, 1399/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of iron supplementation during menstrual bleeding on bleeding and hemoglobin level in students: A Randomized Clinical Trial

Public title
The effect of iron supplementation during menstrual bleeding on bleeding and hemoglobin level
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Conscious and free written satisfaction to participate in the study Lack of vitamin intake and iron supplementation in the last three months Lack of pregnancy and lactation Not using oral and injectable steroid hormonal drugs Lack of known parasitic and infectious diseases Lack of blood diseases such as thalassemia and hemophilia No known history of psychiatric disorders Lack of endocrine disorders such as diabetes and thyroid problems Lack of Contraindications Iron Consumption: Receiving blood frequently -Intake of intravenous iron-absorption disorder and excessive iron storage such as hemochromatosis Not being a smoker Not taking mineral supplements at the moment Not taking herbal medicines and supplements for two weeks before the start of the study and throughout the study BMI between 18.5 to 25 kg / m2 Hemoglobin greater than or equal to 12 grams per deciliter (not being anemic) Having a normal menstrual cycle between 21-35 days and no known history of menorrhagia Not having a recent history of major surgery and an accident leading to a blood transfusion Lack of digestive problems (risk of iron deficiency disorders) -No use of tampons or menstrual cups
Exclusion criteria:
The occurrence of allergic reactions to iron tablets Forget about taking more than one iron pill per cycle Take emergency contraceptive pills in each cycle
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocating individuals to two intervention and control groups will be randomly simple and using a lottery. Put 80 sheets of paper with code 1 and 80 pieces of code 2 in a bowl and mix well. Each participant is asked to remove one of the sheets from the container so that they are randomly assigned to one of the iron pill use groups in the first 4 days of menstrual bleeding or the use of Plus Bo in the first 4 days of menstrual bleeding.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The manufacturer of the drug, taking into account codes 1 and 2, closes the iron and pharmaceutical tablets and provides them to the participants in the project by a researcher or information collector. Questionnaires 1 and 2 will also be specified in the questionnaires. The completed questionnaires are then provided to the statistical consultant for analysis, and at the end, after the results have been determined, iron tablets and pharmaceuticals are identified. Thus, the women participating in the project, the researcher, the information gathering colleague and the statistical consultant of the type of medicine will be unaware and study the three Socors.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences
Street address
No. 33, Alley 41, Mostafa Khomeini St
City
Rafsanjan
Province
Kerman
Postal code
7714668168
Approval date
2020-07-13, 1399/04/23
Ethics committee reference number
IR.RUMS.REC.1399.077

Health conditions studied

1

Description of health condition studied
Taking iron supplements during menstrual bleeding

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Menstrual bleeding rate
Timepoint
Before the intervention and after each intervention (three menstrual cycles)
Method of measurement
Higham chart (pictorial blood assessment chart)

2

Description
Blood hemoglobin level
Timepoint
Before the intervention and one week after taking the last iron pill or placebo
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ferrous sulfate iron tablets containing 50 mg of iron ions are prepared by Amin Pharmaceutical Company. The intervention group will be given 12 iron pills to take three menstrual cycles. The time to take iron pills is in the first 4 days of menstrual bleeding.
Category
Treatment - Drugs

2

Description
Control group: Control group: Ferrosulfate iron tablet placebo is provided by Amin Pharmaceutical Company. The control group will be given 12 placebos for three menstrual cycles.The time of taking the placebo is in the first 4 days of menstrual bleeding
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan University of Medical Sciences
Full name of responsible person
Elnaz Mokhtarkalimi
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Sponsors / Funding sources

1

Sponsor
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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
Rafsanjan 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

Rafsanjan University of Medical Sciences
Full name of responsible person
Marzeyeh Loripoor
Position
Assistant Professor
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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