Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The comparison of effectiveness of monthly and weekly prescription method of iron complementary on Hemoglobin level and Mood of girl students : A Randomized, double blind controlled trial

Protocol summary

Summary

The aim of this study is to comparison between two method of iron complementary prescription on the level of hemoglobin and mood in girl students. This study is a Randomized, double blind controlled trial . Participants are girl students living in dormitories of Tabriz University of Medical Sciences. The main inclusion criterion includes hemoglobin below 12 gr/dl an the main exclusion criterion is the diagnosis of other types of anemia during the study. The number of participants will be 225. After signing conscious consent and taking blood samples from students (by laboratory) those whose hemoglobin level is under 12g/dl will enter the study. Participants in 3 groups will receive weekly iron complementary, menstrual iron complementary and placebo. Weekly iron complementary group will receive iron pills, once every week and placebo will be taken in the first 4 days of each menstrual bleeding period. Menstrual iron complementary group will be taken iron pills in the first 4 days of each menstrual bleeding period and placebo in a specific day every week. Placebo group will receive a pill (the same color as iron pill) in the first 4 days of each menstrual period and receive the other color (the same color as iron pill) in a specific day weekly. The intervention will last 4 month. After intervention, the level of hemoglobin and mood status will be compared between 3 groups before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210137618N4**
Registration date: **2012-11-06, 1391/08/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-11-06, 1391/08/16

Registrant information

Name
Soheila Bani
Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Research Deputy of Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-10, 1391/08/20

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effectiveness of monthly and weekly prescription method of iron complementary on Hemoglobin level and Mood of girl students : A Randomized, double blind controlled trial

Public title

The effects of iron complementary on hemoglobin level

and mood

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Students living in dormitories of Tabriz university of medical sciences, Not using vitamin and iron complementary in the last 3 month, Not using oral or injection steroidal hormones, Not using IUD, Not existence of a hepatic, infectious or parasitic diseases in the time of study, Not existence of hematologic disorders such as thalassemia or hemophilia, any contraindication iron complementary, Not existence psychological disorders, Not existence systemic disorders which can affect menstrual bleeding such as diabetes, thyroid disorders, hyperadrenalism,... , participants with signs and symptoms of anemia which investigator finds in clinical examination(assessing color of mucosa, nails, conjunctive), participants with hemoglobin below 12g/dl. Exclusion criteria: Not being interested to continue (leaving study), diagnosis of other types of anemia during the study, diagnosis of systemic, infectious, parasitic or hepatic disorders during study.

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **225**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy of Tabriz University of Medical Sciences

Street address

Tabriz, Golgasht st, Tabriz University Of Medical Sciences, No 2 Building, 3 floor, Deputy Of Research

City

Tabriz

Postal code

51665118

Approval date

2012-10-15, 1391/07/24

Ethics committee reference number

91111

Health conditions studied

1

Description of health condition studied

Anemia

ICD-10 code

D50

ICD-10 code description

Iron deficiency anaemia

Primary outcomes

1

Description

Hemoglobin level

Timepoint

Once before the intervention and second time 4 months after beginning the intervention

Method of measurement

Based on result laboratory by Cell counter device model H1

2

Description

Mood

Timepoint

Once before the intervention and second time 4 months after beginning the intervention

Method of measurement

Based on POMS SF questionnaire

Secondary outcomes

1

Description

Menstrual bleeding level

Timepoint

Once before the intervention and second time 4 months after beginning the intervention

Method of measurement

Based on Higham questionnaire

Intervention groups

1

Description

Intervention group: Ferfolic pills containing 60 mg ferrous sulfat and 400 µg folic acid, Will be used in one group one pill every week and the other group, one pill in the first 4 days of menstrual bleeding period up to 4 month

(16 week).

Category

Treatment - Drugs

2

Description

Control group: Placebo contains pharmacologically useless substances such as lactose, starch and Avisel (micro crystalin selulose), This materials are used for pharmacological and non pharmacological (placebo) pills. Placebo will be used in one group, one pill every week and the other group one pill in the first 4 days of menstrual bleeding period and in placebo group the both weekly and in the first 4 days of menstrual bleeding up to 4 month (16 week).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar dormitoy of Tabriz University of Medical Sciences

Full name of responsible person

Ayemeh Hassanpour seiah estalkhi, Master of sciences student in midwifery

Street address

Kosar dormitoy, end of South Shariati street, side of Faculty of Nursing and Midwifery

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Sakineh Mohamad Alizadeh

Street address

Faculty of Nursing and Midwifery, South Shariati street

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ayemeh Hassanpour seiah estalkhi

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Master of sciences student in midwifery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty