# 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
**Country**
Iran (Islamic Republic of)
**Phone**
+98 41 1479 6770
**Email address**
banis@tbzmed.ac.ir


**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

**City**

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

**Position**

Master of sciences student in midwifery

**Other areas of specialty/work**

**Street address**

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Tabriz

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## Person responsible for scientific inquiries

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Sohiela Bani

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## Person responsible for updating data

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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*