

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Comparison of hemoglobin and hematocrit in two groups receiving vitamin B6 and iron with iron in women with iron deficiency anemia referred to health and medical centers of Gonabad city in 1398

Protocol summary

Study aim

Determination of hemoglobin and hematocrit in the two groups receiving vitamin B6 and iron with iron in women with iron deficiency anemia

Design

The present study will be a clinical trial with two equal arms of samples selected first by the simple method of non-pregnant women with iron deficiency anemia referring to health centers of Gonabad city with ferritin level less than 12 micrograms per liter, and to evaluate vitamin B efficacy; 66 women. The randomized block allocation method will be divided into intervention and control groups.

Settings and conduct

Women with iron deficiency anemia will have informed consent if they have inclusion criteria and desire to participate in the study and will be divided into intervention and control groups. Complete blood counts will be performed again after one month. To check the complete blood cell count, all women will receive 2 cc of blood in an EDTA vacuum tube and will be tested with the BC5800 CBC manufacturing in 2015.

Participants/Inclusion and exclusion criteria

MCV <80fl, MCH <27pg, MCHC <33g / dl, ferritin <12mcg / l and HB = 8-12gr / Exclusion criteria: cut or change medication, Not willing to participate in the study

Intervention groups

Intervention group will be given 100 mg iron tablets daily (ferrous sulfate) and 80 mg vitamin B6 tablet (pyridoxine hydrochloride manufactured by Iran Hormone Company) and control group will receive 100 mg iron.

Main outcome variables

By determining the effect of vitamin B6 on CBC, it can be used in the treatment of anemia to achieve a shorter and less costly treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190730044382N1**

Registration date: **2019-08-27, 1398/06/05**

Registration timing: **retrospective**

Last update: **2019-08-27, 1398/06/05**

Update count: **0**

Registration date

2019-08-27, 1398/06/05

Registrant information

Name

Asma Salar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5728 8961

Email address

salar.a.stu@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-04, 1398/05/13

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of hemoglobin and hematocrit in two groups receiving vitamin B6 and iron with iron in women with iron deficiency anemia referred to health and medical centers of Gonabad city in 1398

Public title

The effect of vitamin B6 on anemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

MCV <80fl and MCH <and MCHC <33g /dl and ferritin <12mcg / l HB = 8-12gr / dl No history of gastrointestinal bleeding and gastrointestinal surgery and diseases associated with malabsorption including celiac based on patient statement and records No drug and hemoglobin-increasing agents in the last month (blood transfusion, intravenous administration of iron, iron tablets and erythropoietin in the last one month) Lack of any hereditary anemia (including thalassemia and tuberculosis anemia ... based on patient's statement) Lack of chronic disease based on history Not taking other medicines (based on patient's statement or accompanying medication) Not taking supplements, including multivitamins and calcium, on a patient statement No smoking No alcohol or coffee utilization No pregnant

Exclusion criteria:

cutt or change medication Not taking iron tablets in the control group and the case even once Not taking vitamin B6 in the case group for even one time Not willing to participate in the study further

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Santo Road Asian Margin

City

Gonabad

Province

Razavi Khorasan

Postal code

5643312237

Approval date

2019-07-27, 1398/05/05

Ethics committee reference number

IR.GMU.REC.1398.071

Health conditions studied

1

Description of health condition studied

Iron deficiency anemia

ICD-10 code

D50.9

ICD-10 code description

Iron deficiency anemia, unspecified

Primary outcomes

1

Description

Percentage of people with increased hemoglobin

Timepoint

At baseline and 30 days after intervention

Method of measurement

To check the complete blood cell count, all women will receive 2 cc of blood in an EDTA vacuum tube and will be tested with the BC5800 CBC manufacturing in 2015.

2

Description

Percentage of people with increased hematocrit

Timepoint

At baseline and 30 days after intervention

Method of measurement

To check the complete blood cell count, all women will receive 2 cc of blood in an EDTA vacuum tube and will be tested with the BC5800 CBC manufacturing in 2015.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will be given 100 mg iron tablets daily (ferrous sulfate) and 80 mg vitamin B6 tablets (pyridoxine hydrochloride manufactured by Iran Hormone Company) for one month.

Category

Treatment - Drugs

2

Description

Control group: 100 mg iron tablets (ferrous sulfate) daily will be given for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohlol Hospital

Full name of responsible person

Farhang Soltanee

Street address

Saadi Street, Vahdat Boulevard,

City

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9691797852

Phone

+98 51 5723 6833

Email

Research@gmu.ac.ir

2

Recruitment center

Name of recruitment center

Fayyaz Bakhsh Health Center

Full name of responsible person

Asma Salar

Street address

Ghadir Square, next to the Blood Transfusion Center, Gonabad Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Asma Salar

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
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Position
MSc student
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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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

No - There is not 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable