Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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
Gonabad
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Postal code
9691797852
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+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
Gonabad University of Medical Sciences adjutancy Education and Research, Asian Road Margin
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9691797852
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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

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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
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