Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of Simultaneous Consumption of “Grape molasses with Ferrus Sulfat Compared with Ferrus Sulfat on Iron Deficiency Anemia in 15-49 years womens .

Protocol summary

Study aim
Investigating the Effect of Simultaneous Consumption of “Grape molasses with Ferrus Sulfat Compared with Ferrus Sulfat on Iron Deficiency Anemia .

Design
A double-blind clinical trial. From patients with anemia confirmed by blood test, eligible individuals are selected and then randomly assigned to one of two intervention or control groups. Intervention group: Iron tablets with grape juice and Control group: Iron tablets with placebo. Sample size: 80 phase of clinical trial

Settings and conduct
Location: Hematology Specialty Clinic of Imam Khomeini Hospital in Urmia. The patient's general tendency at week 0 and 4, severity of anemia based on blood hemoglobin at week 0 and 4, and drug side effects at week 4, are assessed. The types of medicines are blind.

Participants/Inclusion and exclusion criteria
Completion of informed consent form by women with anemia with hemoglobin 10-12 and age 15-49 years

Intervention groups
The intervention group received iron tablets (3 times a day fasting) and grape juice (10 cc three times a day in warm water) three times a day. (1 hour before breakfast, lunch, and dinner) and the control group received iron tablets (fasting 3 times daily) and placebo syrup (10 cc three times daily in warm water). (1 hour before breakfast, lunch and dinner).

Main outcome variables
blood hemoglobin

General information

Reason for update

Acronym
GMAS

IRCT registration information
IRCT registration number: **IRCT20200120046205N1**
Registration date: **2020-01-30, 1398/11/10**
Registration timing: **prospective**

Last update: **2020-01-30, 1398/11/10**
Update count: **0**

Registration date
2020-01-30, 1398/11/10

Registrant information

Name
Rasoul Pourhakim rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3343 1734

Email address
rasoul.pourhakim@shahed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-08, 1398/11/19

Expected recruitment end date
2020-10-21, 1399/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of Simultaneous Consumption of “Grape molasses with Ferrus Sulfat Compared with Ferrus Sulfat on Iron Deficiency Anemia in 15-49 years

womens .

Public title
Investigating the Effect of “Grape molasses on Iron Deficiency Anemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Iron Deficiency Anemia mild type age 15-49 years
Exclusion criteria:
Diabetic Individuals pregnancy
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study participants are dividing into two groups of grape molasses and placebo with simple random method by using the random number table.For randomization, each drug or placebo is assigned a specific code computer program and is included in the label containing the consumption information. The researcher and patients are not aware of any drug or placebo codes
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher and study participants (patients) are unaware that they have been given Grape molasses or placebo.(double blind trial)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahed University
Street address
Shahed University, Opposite to Imam Khomeini holy shrine, Persian Gulf highway (Tehran-Qom)
City
Tehran
Province
Tehran
Postal code
331911865
Approval date
2019-12-23, 1398/10/02
Ethics committee reference number
IR.SHAHED.REC.1398.108

Health conditions studied

1

Description of health condition studied
iron Deficiency Anemia
ICD-10 code
D50
ICD-10 code description
Iron deficiency anemia

Primary outcomes

1

Description
Blood hemoglobin
Timepoint
At the beginning of the study and one month after the intervention
Method of measurement
blood test

Secondary outcomes

1

Description
Side effects of the drug
Timepoint
Before the intervention and one month after the intervention
Method of measurement
Medication Complications Questionnaire

Intervention groups

1

Description
The intervention group: this group receives iron tablets with grape molasses (10 cc in a glass of lukewarm water) three times a day (1 hour before breakfast, lunch, and dinner) for one month.
Category
Treatment - Drugs

2

Description

Control group: this group receives iron tablets with placebo syrup (10 cc in a glass of lukewarm water) three times a day (1 hour before breakfast, lunch, and dinner) for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty Blood Clinic, Imam Khomeiny hospital

Full name of responsible person

Rasoul Pourhakim rezaei

Street address

Imam Khomeini hospital, Ershad Ave., Modarres Blvd

City

urmia

Province

West Azarbaijan

Postal code

5715789397

Phone

+98 44 3346 9931

Fax

+98 44 3345 7277

Email

emam-h-urm@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Imam Khomeini holy shrine, Persian Gulf highway (Tehran-Qom), Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 5105

Email

info@shahed.ac.ir

Web page address

http://shahed.ac.ir/research/Pages/Home.aspx

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Rasoul Pourhakim rezaei

Position

PhD Candidate of Iranian Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Shahed University, Opposite to Imam Khomeini holy shrine, Persian Gulf highway (Tehran-Qom), Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 4055

Email

Rasulpurhakim@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Fatemeh Emadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Shahed University, Opposite to Imam Khomeini holy shrine, Persian Gulf highway (Tehran-Qom), Tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Phone
+98 21 5121 2600
Email
fatemeh12emadi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Rasoul Pourhakim rezaei
Position
Assistant of Traditional Medicine
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Shahed University, Opposite to Imam Khomeini holy shrine, Persian Gulf highway (Tehran-Qom), Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 4055
Fax
Email
Rasoul.pourhakim@shahed.ac.ir

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