

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Phone**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