

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of synbiotic capsule on the status of hematologic indices of anemia in women with iron deficiency anemia referring to in City Level Labs Mahallat

Protocol summary

Study aim

The effect of synbiotic capsule on hematologic status of anemia in with iron deficiency anemia referring to Imam Khomeini Hospital in Mahalat

Design

Trial without control group, simple randomization, without blinding

Settings and conduct

Workplace Design: Hospital Methods: 10% of the sample size was calculated and referrals from cases with iron deficiency anemia with a hemoglobin concentration of 10 to 12 mg / dl were recorded from the total list with a number ranging from 1 to 9. The baseline and the multiples of the sample will continue. The general information questionnaire, oral frequency questionnaire and ethical consent will be completed and a training session on dietary intake and supplement intake will be held for all women. All people are asked to notify the practitioner of the plan in the event of illness, medication, or any form of supplementation by the physician, or any changes that may affect the plan. Anthropometric measurements (including weight and height), biochemical variables (RBC, HB, HCT, MCV, MCH, MCHC, RDW, Ferritin, IRON, TIBC) and end of study will be reviewed. All women receive 2 capsules of synbiotic daily for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 20-35 years old, with hemoglobin concentration greater than 12-12 mg / dl
Exclusion criteria: no supplementation, blood loss within 3 months, disease

Intervention groups

Synbiotics Supplement

Main outcome variables

RBC , HB , HCT , MCV , MCH , MCHC , RDW index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190807044465N1**

Registration date: **2019-10-26, 1398/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-26, 1398/08/04**

Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

sodabeh amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4322 3026

Email address

sodabehamiry@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic capsule on the status of hematologic indices of anemia in women with iron deficiency anemia referring to in City Level Labs Mahallat

Public title

The effect of synbiotic on the status of indices of anemia in women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women with iron deficiency anemia referred to in City Level Labs Mahallat

Exclusion criteria:

Women under 20 and over 35 years

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

Biochemical variables including (RBC, HB, HCT, MCV, MCH, MCHC, RDW, Ferritin, IRON, TIBC

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics of Arak University of Medical Sciences

Street address

jomhhori Avenue - Jihad Construction Str

City

Mahallat

Province

Markazi

Postal code

37816-66369

Approval date

2019-01-23, 1397/11/03

Ethics committee reference number

IR.ARAKMU.REC.1398.088

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

RBC index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

2

Description

HB index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

3

Description

HCT index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

4

Description

MCV index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

5

Description

MCH index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

6

Description

MCHC index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

7

Description

RDW index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

8

Description

Ferritin index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

9

Description

IRON index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

10

Description

TIBC index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Biochemical test

11

Description

BMI index

Timepoint

Baseline - 12 weeks after intervention

Method of measurement

Balance and meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women 20-35 years old with iron

deficiency anemia/ Synbiotic supplement as Familact capsule contains high levels (109 CFU) of different probiotics prescribed in doses of 500 mg / 2 daily / Bio Fermentation Company - Iran

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Mahallat

Full name of responsible person

Sodabeh Amiri

Street address

Jomhori Street

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Sodabehamiry@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Azizi Soleiman

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Grant name

Grant code / Reference number

640

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

No

Title of funding source

Arak Medical 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
Arak University of Medical Sciences
Full name of responsible person
Soudabeh Amiri
Position
Expert
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

BMI, Biochemical index

When the data will become available and for how long

3 Month

To whom data/document is available

Researchers plan

Under which criteria data/document could be used

prevention

From where data/document is obtainable

laboratory
What processes are involved for a request to access data/document

Visiting and doing tests
Comments