Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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3781666369
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Email
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
Street address
Jomhori Street
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Sodabehamiry@yahoo.com
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

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Fatemeh Azizi Soleiman

Position
Science Committee

Latest degree
Ph.D.

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Person responsible for updating data

Contact

Name of organization / entity
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Mahbobeh Rahmani

Position
Expert

Latest degree
Master

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Health Technology Assessment

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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