Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

The effects of Synbiotic supplementation on blood and milk minerals and trace elements of lactating mothers

Protocol summary

Study aim

Evaluation of the effect of synbiotic supplementation on blood and milk minerals and trace elements of lactating mothers.

Design

Two arm parallel group clinical randomized trial, triple blinded, phase 3 on 80 lactating mothers. For randomization, permuted block randomization method was used.

Settings and conduct

80 lactating mothers aged 18-35 years with 1–2-month-old infants who came to Azadshahr clinic of Yazd, included in the study. Mothers were divided into two groups based on permuted block randomization. Demographic information and infants' data were obtained by a questionnaire. Samples of mothers breast milk and plasma were taken at baseline and at the end of the study for evaluation of the levels of manganese,iron,copper,calcium, magnesium in milk and blood by atomic absorption spectrometry. Weight, Height and head circumference of infants were measured at baseline, 1,6, 12 and 36-60 months after intervention. Furthermore,BMI of mothers were measured at baseline, and after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy lactating mothers aged 18-35 years old with 1-2 months old exclusive breast fed infant. Exclusion criteria: Mothers with chronic disease, taking any other multivitamin or mineral supplement, taking antibiotic less than 2 weeks prior to the study.

Intervention groups

Intervention group: Synbiotic capsule, LactoFem (109 CFU of Lactobacillus fermentum, plantarum, acidophilus, gasseri, rhamnosus, bulgaricus, casei and Fructooligosaccharides) manufactured by Zist Takhmir company, once daily for 30 days. Control group: Placebo capsule which was similar in color, shape and taste with synbiotic capsule, manufactured by the same company, once daily for 30 days. Both groups took iron and multivitamin supplements, according to the national protocol.

Main outcome variables

Mean serum and milk levels of Mg, Mn, Ca, Fe, and Cu

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181020041387N2**
Registration date: **2024-06-28, 1403/04/08**
Registration timing: **retrospective**

Last update: **2024-06-28, 1403/04/08**
Update count: **0**

Registration date

2024-06-28, 1403/04/08

Registrant information

Name

Seyedeh Zalfa Modarresi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

zmodarres@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date
2019-09-21, 1398/06/30
Trial completion date
2022-11-22, 1401/09/01

Scientific title
The effects of Synbiotic supplementation on blood and milk minerals and trace elements of lactating mothers

Public title
The effects of Synbiotic on minerals
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers who have 1-2 months old infants Mothers who have exclusively breast fed infants Mothers aged 18-35 years old. Mothers who have Infants born in more than 36 weeks of gestational age Mothers whom their infants birth weight was more than 2500 gram.
Exclusion criteria:
Mothers with chronic disorders Taking Antibiotics 2 weeks prior to the study by mothers. Taking any other multivitamin and mineral supplements except that is administered by the health team for all lactating mothers. History of hospitalization in infants
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**
Actual sample size reached: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the group allocation is performed through permuted block randomization at an assignment ratio of 1:1. patients were randomly divided into 2 groups: intervention group (as synbiotic supplement group) and control group (as placebo group) (named groups A and B). Group assignment was done through closed envelopes. Six of the four combinations of intervention and placebo groups A and B were determined AABB ABAB ABBA BBAA BABA BAAB (With block random assignment using a random number table). Block size was 4. For allocation concealment, the randomisation codes were kept in opaque, sealed, sequentially numbered envelopes.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients who enrolled in the study based on the randomization list received sealed envelopes from the secretory ward and presented them to the researcher. The researcher administered the drugs labelled as A or B according to the codes within the envelopes. Both the drugs (synbiotic supplement and the placebo capsules) were identical in appearance, shape, color, and packaging, with the only difference being the manufacturer-assigned codes. In this study, the participants, healthcare providers, the researcher doctor who provides the drug to the patients and is responsible for the follow-up of the patient-, data collectors, data and safety monitoring board and outcome assessors are not aware of the assigned groups. After the completion of the study and analysis by the statistician, the codes are determined by the manufacturing company.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of school of medicine-Shahid Sadoughi University of Medical Sciences
Street address
School of Medicine, Shohadaye Gomnam BLVD., Alem Square, Safaeiyeh, Yazd, Iran.
City
Yazd
Province
Yazd
Postal code
8915173143
Approval date
2017-11-29, 1396/09/08
Ethics committee reference number
IR.SSU.MEDICINE.REC.1396.173

Health conditions studied

1

Description of health condition studied
Lactating mothers
ICD-10 code
Z39.1
ICD-10 code description
Encounter for care and examination of lactating mother

Primary outcomes

1

Description
Plasma Calcium (Ca) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

2

Description
Milk Calcium (Ca) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

3

Description
Plasma Magnesium (Mg) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

4

Description
Milk Magnesium (Mg) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

5

Description
Plasma Iron (Fe) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

6

Description
Milk Iron (Fe) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

7

Description
Plasma Copper (Cu) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

8

Description
Milk Copper (Cu) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

9

Description
Plasma Manganese (Mn) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

10

Description
Milk Manganese (Mn) Level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

11

Description
Milk Zinc (Zn) level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

12

Description
Plasma Zinc (Zn) level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

13

Description
Plasma Aluminium (Al) level
Timepoint
Before intervention and one month after intervention
Method of measurement
Atomic absorption spectrometry

Secondary outcomes

1

Description
Infant weight for age Z-score
Timepoint
Before intervention, 1 month after intervention, at the age of 6 and 12 months old

Method of measurement
Scale, weight for age z-score chart

2

Description
Infant height for age Z-score
Timepoint
Before intervention, 1 month after intervention, at the age of 6 and 12 months old
Method of measurement
Meter, Height for age z-score chart

3

Description
Infant head circumference for age Z-score
Timepoint
Before intervention, 1 month after intervention, at the age of 6, 12 and 36 months old
Method of measurement
Meter, head circumference for age z-score chart

4

Description
Infant wheezing episodes
Timepoint
At the age of 12 months
Method of measurement
Parents statement

5

Description
Infant Hospitalization
Timepoint
At the age of 12 months old
Method of measurement
Parents' statement

6

Description
Bronchodilator inhaler usage
Timepoint
At the age of 12 months old
Method of measurement
Parents' statement

7

Description
Infants' taking antibiotics
Timepoint
At the age of 12 months old
Method of measurement
Parents' statement

8

Description
Infants' constipation
Timepoint
before and after intervention
Method of measurement
Parents' statement

9

Description
Mothers' constipation
Timepoint
At the base of intervention, a month after intervention
Method of measurement
Mothers' statement

10

Description
Infants' Eczema
Timepoint
At the base of intervention, a month after intervention
Method of measurement
Mothers' statement

Intervention groups

1

Description
Intervention group: Lactating mothers took one capsule of LactoFem including 109 CFU of probiotics (Lactobacillus fermentum, Lactobacillus plantarum, Lactobacillus acidophilus, Lactobacillus gasseri, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Lactobacillus casei), and prebiotic Fructooligosaccharides (FOS) manufactured by Zist Takhmir Company daily for 30 days.
Category
Prevention

2

Description
Control group: Lactating mothers took one placebo capsule that was similar in shape, tase and color with Lactofem capsules, manufactured by Zist Takhmir company, daily for 30 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Moosa Bin Jafar Health Center
Full name of responsible person
Seyedeh Zalfa Modarresi
Street address
Moosa Bin Jafar Health Center, Mokhaberat street, Azadshahr, Yazd, Iran.
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Province
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Phone
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Fax
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Email
dr.modarres@gmail.com
Web page address
http://www.web.ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Ali Moradi
Street address
Imam Reza building, Daneshjoo Blvd. Imam Hosein Square., Yazd
City
Yazd
Province
Yazd
Postal code
8916188637
Phone
+98 35 3628 7900
Fax
+98 35 3628 8116
Email
dvc.research@ssu.ac.ir
Web page address
http://research.ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Seyedeh Zalfa Modarresi
Position
Pediatric Pulmonologist
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Shahid Sadoughi Hospital, Shahid Ghandi Blvd., Yazd, Iran
City
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
Seyedeh Zalfa Modarresi

Position
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Subspecialist
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dr.modarres@gmail.com

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
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Demographic data and data of primary outcomes
When the data will become available and for how long
Up to six months after publication of the article
To whom data/document is available
Faculty members and students
Under which criteria data/document could be used
Request through academic email
From where data/document is obtainable
Email to dr.modarres@gmail.com
What processes are involved for a request to access data/document
Email to dr.modarres@gmail.com
Comments