

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of probiotic supplementation on presence of supplemented bacteria in breast milk, some of milk's immune and oxidative factors, zinc, selenium, copper, iron, magnesium and calcium concentrations in breast milk, mothers' nutritional status and infants' growth

Protocol summary

Summary

Eighty lactating women admitted to Tabriz health centers who entered to the study based on the inclusion criteria will be randomly divided in probiotic supplementation and placebo groups. The mothers in intervention group will receive one probiotic capsule after breakfast and another one after dinner and mothers in placebo group will receive placebo for 4 weeks. Anthropometric and dietary intake information of mothers and infants will be collected before and after intervention. For determining breast milk probiotic content, IgA, TGFβ1, TGFβ2 and total antioxidant and MDA, zinc, selenium, copper, iron, magnesium and calcium concentrations, 15 cc of breast milk will be collected in a sterile tube by manual expression using sterile gloves in the morning after discarding 5cc. Previously, nipples and mammary areola will be cleaned with soap and sterile water and soaked in chlorhexidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110181197N12**

Registration date: **2011-10-31, 1390/08/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-31, 1390/08/09

Registrant information

Name

Reza Mahdavi

Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Nutrition research center, Agricultural Biotechnology Research Institute of West and North-West Iran

Expected recruitment start date

2011-10-21, 1390/07/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic supplementation on presence of supplemented bacteria in breast milk, some of milk's immune and oxidative factors, zinc, selenium, copper, iron, magnesium and calcium concentrations in breast milk, mothers' nutritional status and infants' growth

Public title

Effect of probiotic supplementation on presence of supplemented bacteria in breast milk, some of milk's immune and oxidative factors, mothers' nutritional status and infants' growth

Purpose

Prevention

Inclusion/Exclusion criteria

The criteria for inclusion of mothers 1) healthy mothers without disease based on medical history 2) having exclusively breastfed infants aged 90 days 3) having exclusively breastfed infants with normal birth weight 4) having exclusively breastfed infants without any chronic disease 5) having exclusively breastfed infants who were full term 6) having second order infants. The criteria for exclusion of mothers 1) mothers consuming antibiotic before and/or in study period 2) mothers who have fever and mastitis before and/or in study period 3) mothers consuming probiotic products 4) mothers consuming antioxidant supplements

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Added at : breast milk zinc, selenium, copper, iron, magnesium and calcium concentrations

Secondary trial Id

Added at : onset and end of study

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Postal code

Approval date

2011-10-21, 1390/07/29

Ethics committee reference number

9041

Health conditions studied

1

Description of health condition studied

Lactating mothers

ICD-10 code

Z39

ICD-10 code description

Care and examination of lactating mother

Primary outcomes

1

Description

Isolation and comparison of supplemented bacteria before and after probiotic supplementation in study groups

Timepoint

onset and end of study

Method of measurement

PCR

Secondary outcomes

1

Description

Determination and comparison of breast milk IgA, TGFβ1, TGFβ2 levels in breast milk before and after probiotic supplementation in two groups

Timepoint

onset and end of study

Method of measurement

IgA= Nephelometry, TGFβ1, TGFβ2 = ELISA

2

Description

Determination and comparison of total antioxidant capacity and MDA levels in breast milk before and after probiotic supplementation in two groups

Timepoint

onset and end of study

Method of measurement

antioxidant capacity = Randox kit, MDA= fluorometry

3

Description

Determination and comparison of lactating mothers' BMI, energy and macronutrient intake before and after probiotic supplementation in two groups

Timepoint

onset and end of study
Method of measurement
Food record questionnaire

4

Description
Determination and comparison of infants' anthropometric indices before and after probiotic supplementation in two groups

Timepoint
onset and end of study

Method of measurement
Weight= electronic scales, Height= Scale (SCHORR)

5

Description
Added at 2013-08-06: zinc, selenium, copper, iron, magnesium and calcium concentrations in breast milk

Timepoint
Added at 2013-08-06: onset and end of study

Method of measurement
Added at 2013-08-06: Atomic absorption (Calcium: kit)

Intervention groups

1

Description
Intervention= probiotic capsule(112x106), 4 weeks, twice a day

Category
Treatment - Drugs

2

Description
Control group= placebo, 4 weeks, twice a day

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Laleh Health Center
Full name of responsible person
Dr Reza Mahdavi (PhD in nutrition, Professor)
Street address
Health and nutrition faculty-Tabriz university of medical sciences- Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nutrition Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Dr Alireza Ostadrahimi

Street address
Health and Nutrition faculty-Tabriz University of Medical Sciences

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Nutrition Research Center, Tabriz University of Medical Sciences

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Agricultural Biotechnology Research Institute of West and North-West Iran

Full name of responsible person
Dr Amin Hejazi

Street address
Across the 29 Bahman hospital-Tabriz

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Agricultural Biotechnology Research Institute of West and North-West Iran

Proportion provided by this source

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Reza Mahdavi

Position

Professor of nutrition sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty