

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7584

##### Email address

mahdavi@tbzmed.ac.ir

##### 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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*