

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Effect of Lactobacillus Acidophilus Probiotic Supplementation on the Incidence of Urinary Tract Infection in the Postpartum Period: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

To determine the effect of Lactobacillus acidophilus probiotic on the occurrence of urinary tract infections during the postpartum period

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 234 patients. The randomizer software will be used for randomization.

Settings and conduct

This study will be performed in Al-Zahra and Taleghani hospitals and 29-Bahman of Tabriz. Participants will take a 500 mg probiotic or placebo capsule a day for 8 weeks. The participants, researcher and data analyst will be blinded. Drugs and placebo will be similar in appearance and will be prepared in similar opaque bottles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Childbirth in the last 48 hours; Negative urine culture at the time of entering the study. Exclusion criteria: Regular consumption of dairy products 2 weeks before the start of the study; Allergy to probiotics; Conditions requiring additional antibiotics; Use of any immunosuppressive drugs; Having high-risk diseases

Intervention groups

One group as the intervention group will receive probiotic capsule of 500 mg once a day and one group as the control group will receive placebo capsule similar to the treatment group for 8 weeks.

Main outcome variables

Frequency of urinary tract infections

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N81**

Registration date: **2024-01-04, 1402/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-04, 1402/10/14**

Update count: **0**

Registration date

2024-01-04, 1402/10/14

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-31, 1402/10/10

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Lactobacillus Acidophilus Probiotic Supplementation on the Incidence of Urinary Tract Infection in the Postpartum Period: A Randomized

Controlled Clinical Trial

Public title

Effect of Probiotic Supplementation on the Incidence of Urinary Tract Infection in the Postpartum Period

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Childbirth experience in the last 48 hours Negative urine culture at the time of entering the study

Exclusion criteria:

Regular consumption of fermented dairy products containing probiotics, especially yogurt, cheese, and buttermilk 2 weeks before the start of the study Allergy to any of the products containing probiotics Conditions that require additional antibiotics during the puerperal period Use of any immunosuppressive drugs Having high-risk disease conditions

Age

From **10 years** old to **54 years** old

Gender

Female

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **234**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation sequence will be determined using Randomizer computer software and random block method with block sizes of 4 and 6 and with allocation ratio of 1:1 and stratification based on the type of delivery (vaginal or caesarean section) and sampling setting (hospitals of Al-Zahra, Taleghani or 29 Bahman). Probiotic supplements or placebos will be prepared in sequentially numbered packages based on the allocation sequence. Eligible people will enter the random chain in the order of entering the study and will receive the specified intervention.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This research is a triple-blind randomized trial (participant, intervention implementer, data collector and analyst will be unaware of the type of intervention received by groups). Blinding will be performed by a pharmacist colleague at Faculty of Pharmacy of Tabriz University of Medical Sciences through probiotic and placebo capsules in terms of color, appearance, smell, and taste.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Reaserch department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht street, Azadi street

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East Azarbaijan

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5138947977

Approval date

2023-12-06, 1402/09/15

Ethics committee reference number

IR.TBZMED.REC.1402.651

Health conditions studied

1

Description of health condition studied

Urinary tract infection

ICD-10 code

O86.2

ICD-10 code description

Urinary tract infection following delivery

Primary outcomes

1

Description

The incidence of urinary tract infection (cystitis, pyelonephritis, asymptomatic bacteriuria)

Timepoint

During the study and two months after the start of the intervention

Method of measurement

Urine culture and checklist of urinary infection symptoms

Secondary outcomes

1

Description

Breastfeeding performance

Timepoint

Two months after the start of the intervention

Method of measurement

Breastfeeding performance questionnaire

2**Description**

Quality of life

Timepoint

Two months after the start of the intervention

Method of measurement

Quality of life questionnaire

3**Description**

Appropriate weight gain for the baby

Timepoint

Two months after the start of the intervention

Method of measurement

Scale

4**Description**

The level of satisfaction with the received intervention

Timepoint

Two months after the start of the intervention

Method of measurement

Satisfaction checklist

5**Description**

Side events

Timepoint

During the study

Method of measurement

Checklist of side events

Intervention groups**1****Description**

Intervention group: The intervention group will take a 500 mg probiotic capsule of Lactobacillus acidophilus strain daily with a glass of water at lunch for 8 weeks. Lactobacillus acidophilus sachet will be prepared from Pishgaman Pakhsh Sadigh Pharmaceutical Company, which is the representative of Christian Hansen Company in Iran.

Category

Treatment - Drugs

2**Description**

Control group: The control group will take a 500 mg placebo capsule (containing corn starch) daily with a glass of water at lunch for 8 weeks. Placebo will be prepared by Faculty of Pharmacy of Tabriz University of

Medical Sciences.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

AlzahraTherapeutic Educational Center

Full name of responsible person

Fatemeh Borhani Soureh

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2**Recruitment center****Name of recruitment center**

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3**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Fatemeh Borhani Soureh

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
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Professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available