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

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Name of organization / entity
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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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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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3

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Sponsors / Funding sources

1

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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
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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