Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial to evaluate the efficacy of probiotics as an adjunctive treatment in the management of benign prostatic hyperplasia (BPH) in patients attending the urology clinic of Imam Reza Hospital

Protocol summary

Study aim
Improvement of the quality of life of patients with benign prostatic hyperplasia through low-risk and effective probiotic-based treatments

Design
The present study is conducted as a randomized, double-blind, phase III clinical trial with parallel groups on 88 patients. Permuted block randomization is used for randomization.

Settings and conduct
This study is conducted as a double-blind clinical trial on patients with benign prostatic hyperplasia attending the urology clinic of Imam Reza Hospital in Tehran. Informed consent is obtained from the participants, and they are then randomly assigned to one of the study groups. In the intervention group, patients receive Tamsulosin 0.4 mg once daily and Gerilact probiotic twice daily (morning and night) for 12 weeks. Patients in the control group receive only Tamsulosin 0.4 mg once daily. Both the patients and the data evaluator are blinded to group allocation.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the study include a definitive diagnosis of benign prostatic hyperplasia based on clinical symptoms and ultrasound confirmation, and consent to participate in the study. The exclusion criteria include chronic diseases such as prostate cancer and the use of anti-inflammatory drugs before the start of the study.

Intervention groups
Patients in the intervention group receive Tamsulosin 0.4 mg once daily and Gerliact probiotic tablets twice daily (morning and night) for 12 weeks. In the control group, patients only take Tamsulosin 0.4 mg once daily.

Main outcome variables
International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax), post-void residual urine volume (PVR), prostate-specific antigen (PSA).

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260519069453N1**
Registration date: **2026-05-20, 1405/02/30**
Registration timing: **prospective**

Last update: **2026-05-20, 1405/02/30**
Update count: **0**
Registration date
2026-05-20, 1405/02/30

Registrant information
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-06-22, 1405/04/01
Expected recruitment end date
2027-06-22, 1406/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial to evaluate the efficacy of probiotics as an adjunctive treatment in the management of benign prostatic hyperplasia (BPH) in patients attending the urology clinic of Imam Reza Hospital

Public title
Evaluation of the efficacy of probiotics in the management of benign prostatic hyperplasia (BPH)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of benign prostatic hyperplasia based on clinical symptoms and confirmation by ultrasonography
Exclusion criteria:
Unwillingness to participate in the research project

Age
From **40 years** old to **75 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The method used is permuted block randomization. For this purpose, two treatment groups, A and B, are defined in blocks as AB and BA. Then, numbers from a random table in the range 0 to 9 are considered. Numbers 0 to 4 are assigned to block AB, and numbers 5 to 9 are assigned to block BA. Random numbers are then selected from the table. If the number 0 appears, it corresponds to block AB, and therefore two individuals enter this block, such that the first individual receives treatment A and the second individual receives treatment B. In the same way, the treatment groups for the remaining participants are determined. Although in this method the number of observations in both groups will be equal, because of the small block sizes, there is a high probability that the person conducting the study may predict the treatment group assignment. To solve this problem, the randomization list is prepared before the start of the study by a blinded individual who is not part of the treatment team. Additionally, the block sizes will be increased.

Blinding (investigator's opinion)
Double blinded

Blinding description
Unwillingness to participate in the research project. This study is conducted in a double-blind manner; such that patients will be unaware of the type of intervention or their assigned group, and the assessor will also remain unaware of the patients' allocation to study groups. In order to maintain blinding, the intervention in both groups is designed to be as similar as possible in terms of appearance, method of presentation, and implementation conditions, and the interventions are recorded with specific codes, and the information related to the codes is kept by an individual outside the assessment process until the end of data collection and analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Islamic Republic of Iran Army University of Medical Sciences
Street address
Etemadzadeh St., Dr. Fatemi St., Shariati St.
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Approval date
2025-06-29, 1404/04/08

Ethics committee reference number
IR.AJAUMS.REC.1404.084

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia

ICD-10 code
N40.1

ICD-10 code description
Enlarged prostate with lower urinary tract symptoms

Primary outcomes

1

Description
Severity of disease symptoms

Timepoint
At the beginning of the study (before the start of the intervention) and 12 weeks after the start of drug administration

Method of measurement
Standard International Prostate Symptom Score questionnaire

Secondary outcomes

1

Description
Residual urine volume
Timepoint
At the beginning of the study (before the start of the intervention) and 12 weeks after the start of drug administration
Method of measurement
Ultrasonography

2

Description
Maximum urinary flow rate
Timepoint
At the beginning of the study (before the start of the intervention) and 12 weeks after the start of drug administration
Method of measurement
Uroflowmetry

3

Description
Prostate volume
Timepoint
At the beginning of the study (before the start of the intervention) and 12 weeks after the start of drug administration
Method of measurement
Ultrasonography

4

Description
Prostate-Specific Antigen
Timepoint
At the beginning of the study (before the start of the intervention) and 12 weeks after the start of drug administration
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Patients will receive Tamsulosin 0.4 mg once daily and Gerilact probiotic tablets twice daily (morning and evening) for a period of 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive Tamsulosin 0.4 mg once daily for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Parham Montazeri
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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
Artesh 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
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Parham Montazeri
Position
Non-faculty specialist physician
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available