

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the Efficacy of Probiotic and Antibiotic Combination Therapy with Antibiotic Therapy Alone on the Recurrence of Bacterial Vaginosis

#### Protocol summary

##### Study aim

This study aimed to compare the efficacy of probiotic and antibiotic combination therapy with antibiotic therapy alone to prevent the recurrence of bacterial vaginosis.

##### Design

Parallel-arm, Randomized controlled trial

##### Settings and conduct

Gynecological Department of Nishtar Hospital, Multan,

##### Participants/Inclusion and exclusion criteria

Women 18-45 years old having bacterial vaginosis diagnosed according to Amsel's criteria (at least three of the following BV symptoms: Greyish white, thin, homogenous vaginal discharge, vaginal pH >4.5, positive amine test findings, and presence of clue cells (>20%) in a wet smear observed under microscopy, all cured with metronidazole, were enrolled. Patients with a history of allergy against the study drug, pregnant, lactating, menopausal women, history of bleeding from the genital tract of unknown aetiology, women with malignancy of the reproductive tract or any co-morbid condition like AIDS, diabetes, psychiatric illness, or currently using any contraceptive method, and patients using another oral or vaginal probiotic at the time of assessment or receiving antibiotic therapy for another reason were excluded.

##### Intervention groups

In Group A, probiotics (Lactobacillus plantarum PBS067, Lactobacillus rhamnosus LRH020, and Bifidobacterium animalis lactis BL050) were administered once a day for 14 days following antibiotic treatment (Tab Metronidazole 400mg TDS for seven days). A post-antibiotic therapy placebo (dextrose-filled pill) was administered to Group B (n = 52).

##### Main outcome variables

Recurrence of bacterial vaginosis

#### General information

##### Reason for update

##### Acronym

PECABAT-RBV

##### IRCT registration information

IRCT registration number: **IRCT20230814059147N1**

Registration date: **2024-01-10, 1402/10/20**

Registration timing: **retrospective**

Last update: **2024-01-10, 1402/10/20**

Update count: **0**

##### Registration date

2024-01-10, 1402/10/20

##### Registrant information

###### Name

Faisal Ramzan

###### Name of organization / entity

Choudhary Pervaiz Elahi Institute of Cardiology,  
Multan

###### Country

Pakistan

###### Phone

+92 332 6439622

###### Email address

dr.faisalahmadani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-01, 1401/01/12

##### Expected recruitment end date

2023-05-01, 1402/02/11

##### Actual recruitment start date

2022-04-01, 1401/01/12

##### Actual recruitment end date

2023-04-01, 1402/01/12

##### Trial completion date

2023-07-01, 1402/04/10

##### Scientific title

Comparing the Efficacy of Probiotic and Antibiotic Combination Therapy with Antibiotic Therapy Alone on the Recurrence of Bacterial Vaginosis

#### Public title

Comparing the Efficacy of Probiotic and Antibiotic Combination Therapy with Antibiotic Therapy Alone on the Recurrence of Bacterial Vaginosis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Women 18-45 years old Having bacterial vaginosis diagnosed according to Amsel's criteria (at least three of the following BV symptoms: Greyish white, thin, homogenous vaginal discharge, vaginal pH >4.5, positive amine test findings, and presence of clue cells (>20%) in a wet smear observed under microscopy) all cured with metronidazole

##### Exclusion criteria:

History of allergy against the study drug. Pregnant Lactating women Menopausal women History of bleeding from the genital tract of unknown etiology Women with malignancy of reproductive tract or any co-morbid condition like AIDS, diabetes, psychiatric illness Currently using any contraceptive method Patients using another oral or vaginal probiotic at the time of assessment or receiving antibiotic therapy for another reason

#### Age

From **18 years** old to **45 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

- Participant
- Care provider

#### Sample size

Target sample size: **120**

Actual sample size reached: **130**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomized using the lottery method. Each tablet was sealed in a wrapper and by lottery method, will be given to each individual

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Double blinding would involve ensuring that the participants (pregnant women) and care provider are unaware of whether they are receiving the actual drug (antibiotic plus probiotic) or an antibiotic alone. This helps minimize bias and ensures that the results of the study are not influenced by the participants' or researchers' expectations or beliefs.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Ethical Review Board (IERB)

##### Street address

Nishtar hospital, Mutan

##### City

Multan

##### Postal code

66000

#### Approval date

2022-03-01, 1400/12/10

#### Ethics committee reference number

095

## Health conditions studied

### 1

#### Description of health condition studied

Bacterial vaginosis

#### ICD-10 code

N76.0

#### ICD-10 code description

Acute vaginitis

## Primary outcomes

### 1

#### Description

Recurrence of Bacterial Vagniosis

#### Timepoint

at 3 month

#### Method of measurement

Using Amsel Criteria (at least three of the following BV symptoms: Greyish white, thin, homogenous vaginal discharge, vaginal pH >4.5, positive amine test findings, and presence of clue cells (>20%) in a wet smear observed under microscopy)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: antibiotics and probiotics combined: In Group A, probiotics (Lactobacillus plantarum PBS067, Lactobacillus rhamnosus LRH020, and Bifidobacterium animalis lactis BL050) were administered once a day for 14 days following antibiotic treatment (Tab

Metronidazole 400mg TDS for seven days).

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Group B (Antibiotic plus placebo): A post-antibiotic therapy placebo (Dextrose-filled pill)

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Department of Gynae and Obs, Nishtar Hospital, Multan

**Full name of responsible person**

Dr. Saima Ashraf

**Street address**

Nishtar Hospital, Multan

**City**

Multan

**Postal code**

66000

**Phone**

+92 312 8443876

**Email**

saimashahzad35177@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

DME of Nishtar hospital

**Full name of responsible person**

Dr. Mehnaz Khakwani

**Street address**

Nishtar Hospital, Multan

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**Phone**

+92 61 4702121

**Email**

nmu@edu.pk

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

DME of Nishtar hospital

**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**

Nishtar Hospital, Multan

**Full name of responsible person**

Dr. Saima Ashraf

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Nishtar Hospital, Multan

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**Province**

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**Postal code**

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**Phone**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

NISHTAR HOSPITAL, MULTAN

**Full name of responsible person**

Dr. Saima Ashraf

**Position**

ASSISTANT PROFESSOR

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

NISHTAR HOSPITAL, MULTAN

**Full name of responsible person**

Dr. Saima Ashraf

**Position**

ASSISTANT PROFESSOR

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

due to cultural reasons, patients usually hide personal data on individual basis

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Clinical study types, design, and Data statistics

**When the data will become available and for how long**

till the start of 2024, for lifelong

**To whom data/document is available**

all public

**Under which criteria data/document could be used**

only for citations

**From where data/document is obtainable**

google scholar and personal email

**What processes are involved for a request to access data/document**

request on personal email

**Comments**