

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Paaras Suleman

Name of organization / entity

National University of Medical Sciences, Rawalpindi

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		Secondary Ids
		empty
Public title	Comparing the Efficacy of Probiotic and Antibiotic Combination Therapy with Antibiotic Therapy Alone on the Recurrence of Bacterial Vaginosis	Ethics committees
Purpose	Treatment	<u>1</u>
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	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
Age	From 18 years old to 45 years old	Health conditions studied
Gender	Female	<u>1</u>
Phase	2-3	Description of health condition studied Bacterial vaginosis
Groups that have been masked	- Participant - Care provider	ICD-10 code N76.0
		ICD-10 code description Acute vaginitis
Sample size	Target sample size: 120 Actual sample size reached: 130	Primary outcomes
Randomization (investigator's opinion)	Randomized	<u>1</u>
Randomization description	Randomized using the lottery method. Each tablet was sealed in a wrapper and by lottery method, will be given to each individual	Description Recurrence of Bacterial Vagniosis
Blinding (investigator's opinion)	Double blinded	Timepoint at 3 month
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.	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)
Placebo	Not used	Secondary outcomes
Assignment	Parallel	empty
Other design features		Intervention groups
		<u>1</u>
		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

City

Multan

Postal code

66000

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

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 311 8443876

Email

saimashahzad35177@gmail.com

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

Gynecology and Obstetrics

Street address

Nishtar Hospital, Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 311 8443876

Email

saimashahzad35177@gmail.com

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

Street address

Nishtar Hospital, Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 311 8443876

Email

saimashahzad35177@gmail.com

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