Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+92 332 6439622

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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 indivdual

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

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Nishtar Hospital, Multan

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+92 61 4702121

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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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Person responsible for updating data

Contact

Name of organization / entity
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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