Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of the effect of oral metronidazole and vaginal probiotics on the vaginal microbial flora in women with bacterial vaginosis and evaluation of treatment failure

Protocol summary

Study aim
Comparison of the effect of oral metronidazole and vaginal probiotics on the vaginal microbial flora in women with bacterial vaginosis

Design
This study is a randomized trial that is phase 2-3 of the study and block randomization method has been used for randomization

Settings and conduct
This study is a randomized clinical trial study in which women with a diagnosis of bacterial vaginosis are divided into two equal groups of metronidazole and probiotics and then compared in terms of effectiveness of the two treatments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Women with a diagnosis of bacterial vaginosis , 2- Age between 18 and 45 years , 3- No pregnancy or HIV positive , 4- No history of known medical conditions such as epilepsy, diabetes, hypertension and heart and gastrointestinal problems Non-consumption of alcohol and anticoagulants such as coumadin (warfarin), immunosuppressants, vaginal medications, 6- having an IUD Conditions of non-entry : 1- Dissatisfaction with continued cooperation 2- Having serious drug side effects 3- Do not take nutritional supplements 4- Existence of other non-bacterial infections of the vagina 5-Taking antibiotics

Intervention groups
Metronidazole group: Oral treatment with 500 mg metronidazole twice daily for 7 days. Probiotic group: Probiotic vaginal capsules (lactobacillus acidophilus, lactobacillus plantarum, lactobacillus rhamnosos, lactobacillus gasseri) are taken once a day for 14 days.

Main outcome variables
Amsel positive criteria 2- Nugent score 3-The pH of vaginal discharge 4- Existence of homogeneous dilute white-gray discharge 5- Amine test The 6- presence of Clue cells in the vaginal discharge slide

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191104045328N10**
Registration date: **2022-05-10, 1401/02/20**
Registration timing: **prospective**

Last update: **2022-05-10, 1401/02/20**
Update count: **0**

Registration date
2022-05-10, 1401/02/20

Registrant information
Name
Amin Haji seyyed hoseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-22, 1401/03/01
Expected recruitment end date
2022-08-23, 1401/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of oral metronidazole and vaginal probiotics on the vaginal microbial flora in women with bacterial vaginosis and evaluation of treatment failure

Public title
Comparison of the effect of oral metronidazole and vaginal probiotics on the microbial flora of the vagina and evaluation of treatment failure in women with bacterial vaginosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women with a diagnosis of bacterial vaginosis Age between 18 and 45 years No pregnancy or HIV positive No history of known medical conditions such as epilepsy, diabetes, hypertension and heart and gastrointestinal problems Non-consumption of alcohol and anticoagulants such as coumadin (warfarin), immunosuppressants, vaginal medications, having an IUD

Exclusion criteria:
Dissatisfaction with continued cooperation Having serious drug side effects Do not take nutritional supplements Existence of other non-bacterial infections of the vagina Taking antibiotics

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Arak University of Medical Sciences

Street address
Vice chancellor for research, Arak University of Medical Sciences, Basij Square, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2021-07-18, 1400/04/27

Ethics committee reference number
IR.ARAKMU.REC.1400.101

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
Amsel positive criteria

Timepoint
After the intervention

Method of measurement
Clinical examination and swabs biopsy of the vaginal wall

2

Description
Nugent score

Timepoint
After the intervention
Method of measurement
Gram stain scoring system for vaginal swabs

3

Description
The pH of vaginal discharge
Timepoint
Before and after the intervention
Method of measurement
PH meter tape with a range of 1/6 - 6/3 made by Machery – Nagel, Düren, Germany

4

Description
Existence of homogeneous dilute white-gray discharge
Timepoint
Before and after the intervention
Method of measurement
Clinical examination and swabs biopsy of the vaginal wall

5

Description
Amine test
Timepoint
Before and after the intervention
Method of measurement
Production of amine odor by adding 10% KOH solution to vaginal discharge

6

Description
The presence of Clue cells in the vaginal discharge slide
Timepoint
Before and after the intervention
Method of measurement
Preparation of microscopic slide sample from swap vaginal discharge

Secondary outcomes

empty

Intervention groups

1

Description
Metronidazole group: Oral treatment with 500 mg metronidazole twice daily for 7 days.
Category
Treatment - Drugs

2

Description
Probiotic group: Probiotic vaginal capsules (lactobacillus acidophilus, lactobacillus plantarum, lactobacillus rhamnosos, lactobacillus gasseri) are taken once a day for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital, Arak
Full name of responsible person
Dr. Nazila Najdi
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Sponsors / Funding sources

1

Sponsor
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr. Nazila Najdi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2023/4/20 to 2026/4/20 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used

If there are any further questions

From where data/document is obtainable

Dr. Nazila Najdi

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

Letter writing should be done with professors and universities.

Comments