

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 seyed hoseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3366 7583

##### Email address

amin.medstu@gmail.com

##### 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

##### **Street address**

Vice Chancellor for Education, Ayatollah Taleghani Hospital, Arak, Iran

##### **City**

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##### **Province**

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##### **Postal code**

3819691187

##### **Phone**

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##### **Email**

najdinazila@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr Alireza Kamali

##### **Street address**

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

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##### **Email**

alikaliamaliir@yahoo.com

#### **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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Vice Chancellor for Education,Ayatollah Taleghani Hospital, Arak, Iran

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Seidi

**Position**

Arak

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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fatemehseidi@arakmu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Susan Mousavi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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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**