

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 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

Arak

Province

Markazi

Postal code

3819691187

Phone

+98 918 348 2398

Fax

+98 86 3222 2003

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

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

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

Street address

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

City

Arak

Province

Markazi

Postal code

3819691187

Phone

+98 86 3222 2003

Email

najdinazila@gmail.com

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

Street address

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

City

Arak

Province

Markazi

Postal code

3819691187

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

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

Street address

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

City

Arak

Province

Markazi

Postal code

3819691187

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

Soosan.1367@yahoo.com

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