

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 2026

### Effect of probiotic on treatment of bacterial vaginitis and preservation of vaginal bacterial flora in patients treated with metronidazole

#### Protocol summary

##### Study aim

The purpose of this study was to determine the effect of vaginal probiotics (vaginal capsule called lacto flora fem) on improving the role of metronidazole in the treatment of patients with bacterial vaginitis.

##### Design

Randomized, parallel groups trial with blinding

##### Settings and conduct

The study is done in Imam Reza Clinic in patients and medical personnel are kept blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Women with bacterial vaginitis based on Amsel criteria 2. Married and between the ages of 18-48 3. Willing to cooperate Exclusion criteria: 1- Patients with immunodeficiency or HIV positive individuals 2. People with genital and urinary tract infections 3. Antibiotic users within two weeks before entering the study 4. Patients with vaginal candidiasis 5 patients postmonopause 6. Pregnant women or during lactation 7. Patients who do not allow pelvic examination

##### Intervention groups

Intervention group - treated with metronidazole orally twice daily (morning and night) for 7 days and after treatment every three days with a single suppository containing probiotics for 3 weeks. Control group - treated with metronidazole orally twice daily (morning and night) for 7 days and placebo every 3 nights for 3 weeks.

##### Main outcome variables

Clinical symptoms of bacterial vaginitis PH The Amsel Criteria

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180612040071N2**

Registration date: **2020-01-03, 1398/10/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-03, 1398/10/13**

Update count: **0**

##### Registration date

2020-01-03, 1398/10/13

##### Registrant information

###### Name

Parisa Mamivand

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 3616 3625

###### Email address

Parisa.mamivand00@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-26, 1398/09/05

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of probiotic on treatment of bacterial vaginitis and preservation of vaginal bacterial flora in patients treated with metronidazole

##### Public title

Effect of probiotic on treatment of bacterial vaginitis and preservation of vaginal bacterial flora in patients treated with metronidazole

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Women with bacterial vaginitis according to the Amsel criteria married 18-48 years old

### **Exclusion criteria:**

People with immunodeficiency disease and HIV People with genital and urinary tract infections Antibiotic users within two weeks prior to inclusion Patients with candidiasis vaginitis Menopause Pregnant women or during lactation Patients who do not allow pelvic examination

## **Age**

From **18 years** old to **48 years** old

## **Gender**

Female

## **Phase**

3

## **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **128**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Patients with inclusion criteria are randomized by using 4&6 blocks method. Randomization list is prepared before starting the intervention. Patients go under special treatment based on randomize allocation. Patient division conducts by the clerk of the clinic who is blinded to the intervention.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

patients and therapist are blinded to the type of treatment due to similarity of the placebo and Lacto Flora Fem in shape.drug form and route of administration are similar. During assessment gynecologist will be blinded to the treatment.

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

## **Ethics committee**

### **Name of ethics committee**

Ethics committee of Kashan University of Medical Scinces and Health Services

## **Street address**

5th of Qotb -e Ravandi Blvd. P.O.Box: 8715988141, Kashan, IRAN

## **City**

kashan

## **Province**

Isfahan

## **Postal code**

8715988141

## **Approval date**

2019-08-26, 1398/06/04

## **Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1398.067

## **Health conditions studied**

### **1**

## **Description of health condition studied**

bacterial vaginosis

## **ICD-10 code**

N70-N77

## **ICD-10 code description**

Inflammatory diseases of female pelvic organs

## **Primary outcomes**

### **1**

## **Description**

Bacterial vaginitis symptoms

## **Timepoint**

1 month (30days ) after the use of probiotics or placebo

## **Method of measurement**

questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

## **Description**

Intervention group: Patients are treated with metronidazole orally twice daily (morning and night) for 7 days and then treated with probiotic suppository every 3 days for 3 weeks.

## **Category**

Treatment - Drugs

### **2**

## **Description**

Control group: Patients are treated with metronidazole orally twice daily (morning and night) for 7 days and then treated with placebo suppository every 3 days for 3 weeks.

## **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Imam Reza Clinic

**Full name of responsible person**

Dr. Zahra Vahedipoor

**Street address**

Imam Reza Clinic, Beheshti Ave, Kashan

**City**

kashan

**Province**

Isfahan

**Postal code**

1134845764

**Phone**

+98 31 5546 6301

**Email**

zahravahedpoor@g.commail

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr Hamidi

**Street address**

5th of Qotb -Ravandi Blvd. P.O.Box: 8715988141,  
Kashan, IRAN

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Phone**

+98 31 5554 0021

**Fax**

+98 31 5554 1112

**Email**

parisa.mamivand00@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Mehdi Nazeri

**Position**

Assistant Professor of Medical Mycology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Parasitology

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**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Phone**

+98 31 5554 1112

**Fax**

+98 31 5554 1112

**Email**

nazeri\_me@kaums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Mehdi Nazeri

**Position**

Assistant Professor of Medical mycology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

we express only clinical and laboratory outcomes

**When the data will become available and for how long**

Information will be published as article and final report

**To whom data/document is available**

Access limitation is not considered

**Under which criteria data/document could be used**

The final report and article will be available for other researchers

**From where data/document is obtainable**

Library of Kashan University of Medical Sciences

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

Direct referral to the library

**Comments**