

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of bacterial vaginosis recurrence rate between oral versus vaginal probiotic prescription in non pregnant women within reproductive and complaint of vaginal discharge

#### Protocol summary

##### Study aim

Choosing the most appropriate complementary treatment for patients with bacterial vaginosis to reduce relapse rates

##### Design

interventional

##### Settings and conduct

thesis, Mashhad University of medical sciences

##### Participants/Inclusion and exclusion criteria

Master's entry to the study: Married non-pregnant women with bacterial vaginosis, not taking antibiotics during the last 2 weeks, desire to participate in the study, more than 18 years old, not oral tinidazole allergy, no chronic disease and immunodeficiency. no AUB, No use of specific medications or hormone therapy during the last 3 months, no use of medication or vaginal showers within 48 hours prior to examination, no other vaginal infections in clinical examination, regular menstruation, normal gynecological exam, not lactating mothers, good health care state, the level of the personal recognition, the diagnosis and follow-up with the Nugent criteria  
Exclusion criteria: Patient dissatisfaction, discontinuation of treatment, pregnancy, withdrawal from study, antibiotic use, oral metronidazole allergy symptoms, vaginal or probiotic allergy symptoms, use of contraceptives such as diaphragm, IUD ring , Irregular menstruation, Chlamydia or trichomoniasis infection, abnormal vaginal bleeding, immunodeficiency, diabetes, participation in other studies

##### Intervention groups

In intervention group A, metronidazole 500 mg every 12 hours up to 7 days and then continued for two weeks with one vaginal probiotic, and in intervention group B, metronidazole 500 mg every 12 hours to seven days and then continued for 3 weeks with oral probiotics 2 times a day.

##### Main outcome variables

Number of lactobacilli and anaerobes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190202042596N1**

Registration date: **2020-02-03, 1398/11/14**

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

Last update: **2020-02-03, 1398/11/14**

Update count: **0**

##### Registration date

2020-02-03, 1398/11/14

##### Registrant information

##### Name

Mahnaz Boroumand Rezazadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3602 3459

##### Email address

boroumandrm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-27, 1398/11/07

##### Expected recruitment end date

2020-11-27, 1399/09/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparision of bacterial vaginosis recurrence rate between oral versus vaginal probiotic prescription in non pregnant women within reproductive and complaint of vaginal discharge

## Public title

Probiotics for the treatment of vaginal bacteriosis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Laboratory- confirmed bacterial vaginosis Not using natural probiotics

### Exclusion criteria:

No informed consent Having used natural probiotics during the 2 last weeks

## Age

No age limit

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization

## Blinding (investigator's opinion)

Double blinded

## Blinding description

participants, assessors

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Etics committee of Mashhad University of Medical Sciences

##### Street address

No 151, Soroush 46 Ave.,Mehran 1,Mehran Blvd, Mashhad

##### City

Mashhad

## Province

Razavi Khorasan

## Postal code

9188945354

## Approval date

2019-11-05, 1398/08/14

## Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.736

## Health conditions studied

### 1

#### Description of health condition studied

Bacterial Vaginosis

#### ICD-10 code

N76.1

#### ICD-10 code description

واژینیت تحت حاد و مزمن

## Primary outcomes

### 1

#### Description

bacterial vaginosis recurrence

#### Timepoint

before and one month after the treatment

#### Method of measurement

Nugent score

## Secondary outcomes

### 1

#### Description

Evaluation of colonization of lactobacilli, their retention in vagina and establishment of normal vaginal environments within one month interval after treatment

#### Timepoint

one month

#### Method of measurement

Nugent Criteria

## Intervention groups

### 1

#### Description

Intervention group: In the first intervention group, administration of metronidazole 500 mg every 12 hours for up to seven days and then continued for two weeks with one vaginal probiotic daily and in the second intervention group, administration of metronidazole 500g every 12 hours up to seven days. Then continue treatment with oral probiotics 2 times a day for 2 weeks.

#### Category

Treatment - Drugs

## 2

### Description

Control group: Given the confirmation of bacterial vaginosis of patients prior to treatment and investigation of recurrent bacterial vaginosis in patients with Nugent criteria each individual in both intervention groups was considered as their own control.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza hospital

**Full name of responsible person**

Mahnaz Boroumand Rezazadeh

**Street address**

Gynecology Clinic, Imam Reza Hospital

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9188945354

**Phone**

+98 51 3802 2608

**Fax**

+98 51 3802 2608

**Email**

boroumandr@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeid Eslami

**Street address**

Bahonar Blvd.

**City**

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**Province**

Razavi Khorasan

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+98 51 3800 2111

**Email**

boroumandrm@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahnaz Boroumand Rezazadeh

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Floor 6, No.151, Jalale ale ahmad 46 Ave, Jalale ale ahmad Blvd, Mashhad, Iran

**City**

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## Person responsible for scientific inquiries

#### Contact

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Mashhad University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

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**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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