

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparision 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeid Eslami

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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

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

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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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