Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 51 3602 3459

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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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Person responsible for updating data

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Other areas of specialty/work
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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