

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Hamidi

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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

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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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