Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of prebiotic vaginal gel supplement with metronidazole ablet on treatment and recurrence of bacterial vaginosis

Protocol summary

Summary

Objectives: This study aims to determine the effect of complementary therapy of vaginal prebiotic gel with tablet metronidazole on treatment and recurrence of bacterial vaginosis. Design: A double blind randomized controlled trial. Setting and conduct: This study will be conducted in Nasir abad health care center. Eligible women will be randomly assigned into 2 groups of 50 subjects with block sizes of 4 and 6. A person from research team not involved in the recruitment and assigning participants will generate the allocation sequence. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Major inclusion criteria: married; diagnosis of bacterial vaginosis with Amsel criteria and the Nugent scoring system; have willing to participate to study. Exclusion criteria: Having abnormal vaginal bleeding; having other vaginal infections such as candidiasis and trichomoniasis. Interventions: After diagnosis bacterial vaginosis, in addition to metronidazole tablet 250 milligrams 3 times a day (each 8 hours) for 7 days, the patient's will be used prebiotic vaginal gel one applicator (5 milligrams) every night for 7 nights. The control group will use metronidazole tablet 250 milligrams 3 times a day (each 8 hours) for 7 days and placebo vaginal gel one applicator (5 milligrams) every night for 7 nights. Main outcome measures: Clinical and laboratory criteria based on amsel and nugent scoring system; malodon discharge; itching; dyspareunia; having bad smell during sexual and secondary outcomes include: assessment of vaginal pH; client satisfaction; change in Clue cells will be evaluated baseline, 10±1 day after intervention, 12±1 week after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121721917N5**

Registration date: **2016-02-03, 1394/11/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-03, 1394/11/14

Registrant information

Name

Sevil Hakimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of prebiotic vaginal gel supplement with metronidazole ablet on treatment and recurrence of bacterial vaginosis

Public title
Effect of Complementary therapy of vaginal prebiotic gel with metronidazole tablet on treatment and recurrence of bacterial vaginosis: a randomized controlled trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: 18 to 35 years old; married; diagnosis of bacterial vaginosis with contemporary presence of at least 3 out of 4 Amsel criteria and gain score 4 to 6 with clue cells or score 7 to 10 without clue cells in the Nugent scoring system; have willing to participate to study; husband's monogamous; absence of menstruation during the intervention. Exclusion criteria: pregnant or breastfeeding, or menopause; having abnormal vaginal bleeding; consumption of vaginal medication; douching during 48 hours ago; use of alcohol and smoking; use of anticoagulants such as Coumadin and Disulfiram; having other vaginal infections such as candidiasis and trichomoniasis; having known medical disease such as diabetes, thyroid disease and liver diseases according to patient's report; not having tendency to use prebiotic gel.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Azadi avenue, Golgasht street,third floor, number 2 central building,research and technology department, Tabriz University of Medical Sciences
City
Tabriz
Postal code
118-51665
Approval date
2015-06-28, 1394/04/07
Ethics committee reference number
TBZMed.REC.1394.736

Health conditions studied

1

Description of health condition studied
Bacterial vaginosis
ICD-10 code
N73.9
ICD-10 code description
Female pelvic inflammatory disease, unspecified

2

Description of health condition studied
Bacterial vaginosis
ICD-10 code
N74.8
ICD-10 code description
Female pelvic inflammatory disorders in other diseases classified elsewhere

3

Description of health condition studied
Bacterial vaginosis
ICD-10 code
N76.8
ICD-10 code description
Other specified inflammation of vagina and vulva

Primary outcomes

1

Description
Clinical and laboratory criteria based on Amsel and Nugent scoring system
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
Measured by clinical measurements of diseases and laboratory tests

2

Description
Malodon discharge
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
Measured by asking from patient

3

Description
Itching
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
Measured by asking from patient

4

Description
Dyspareunia
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
Measured by asking from patient

5

Description
Having bad smell during sexual intercourse
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
Measured by asking from patient

Secondary outcomes

1

Description
Assessment of vaginal pH
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
pH paper scale

2

Description
Client satisfaction
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
Self-report

3

Description
Change in Clue cells
Timepoint
Baseline, 10±1 day after intervention, 12±1 week after intervention
Method of measurement
direct observation

Intervention groups

1

Description
Intervention group: After diagnosis bacterial vaginosis, in addition to Metronidazole tablet 250 milligrams 3 times a day (each 8 hours) for 7 days, the patient's will be used Prebiotic vaginal gel one applicator (5 milligrams) every night for 7 nights
Category
Treatment - Drugs

2

Description
The control group will use Metronidazole tablet 250 milligrams 3 times a day (each 8 hours) for 7 days and placebo vaginal gel one applicator (5 milligrams) every night for 7 nights
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nasir Abad health care center
Full name of responsible person
Faranak Farhan
Street address
east Hatami, Jannat Abad street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Rashidi Mohammad Reza
Street address
Number 2 central building, third floor, research and technology department, Golgasht street, Azadi avenue, Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source

Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Mostafa Ghare Baghi Parvin
Street address
Alzahra Hospital, South Artesh Ave
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty