

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 envelopes 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

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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

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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****Contact****Name of organization / entity**

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Web page address**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