

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of the effect of oral tablet of Metronidazole with vaginal cream of Jaft concurrent with oral tablet of Metronidazole on results of Bacterial Vaginosis (BV) management in childbearing age women

#### Protocol summary

##### Summary

**Objectives:** In this study, the effect of oral tablet of Metronidazole with vaginal cream of Jaft concurrent with oral tablet of Metronidazole on results of Bacterial Vaginosis (BV) management in childbearing age women will be compared; **Design:** In this Double-blinded (patients and researcher) study, from all the patients referred to the clinic, complaining BV, approximately 950 people will be screened, out of which 168 women with eligible criteria will be randomized into two groups of control and intervention; **Setting and Conduct:** First, Personal information form and inclusion criteria for the study will be completed, Then the tests for diagnosing BV will be done. Treatment for both groups of control and intervention will be done for 7-10 days and finally the tests will be repeated for comparing the symptoms and outcome; **Inclusion criteria:** Women in the childbearing age whom has the Bacterial Vaginosis symptoms and has other inclusion criteria which is emphasized in the study; **Interventions:** Oral Metronidazole tablet 250mg, 2 tablets every 12 hours in both intervention and control groups will be administered. In the intervention group, vaginal cream of Jaft (one Applicator every night) is given. In the control group one Applicator of placebo cream every night is given. This study is a double-blinded placebo controlled clinical trial. The Vaginal creams (Jaft or Placebo), produced by school of pharmacy, are coded in A and B and researcher and the patients are both unaware about which cream ( placebo or Jaft) they are using; **Main outcome:** BV symptoms clinical and in the tests

#### General information

##### Acronym

BV Bacterial Vaginosis

##### IRCT registration information

IRCT registration number: **IRCT2016071428929N1**

Registration date: **2016-09-07, 1395/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-09-07, 1395/06/17

##### Registrant information

###### Name

Atefeh Zare

###### Name of organization / entity

Shiraz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 901 535 4510

###### Email address

atp1990\_zare@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Science budget

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2017-01-20, 1395/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of oral tablet of Metronidazole

with vaginal cream of Jaft concurrent with oral tablet of Metronidazole on results of Bacterial Vaginosis (BV) management in childbearing age women

#### Public title

Comparison of the effect of oral tablet of Metronidazole with vaginal cream of Jaft concurrent with oral tablet of Metronidazole on results of Bacterial Vaginosis (BV) management in childbearing age women

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Willingness to cooperate in the study; Married women of reproductive age (18 - 45); Symptoms of BV on clinical examination and confirmed by Amsel criteria (having three of four criteria) and confirmation by Gram stain and Nugent score should be 7-10; Lack of recent use of oral and topical medications such as Alkaloids, Anti-parasitic, Immunosuppressive drugs and other drugs during the past two weeks, according to the patient report; No sexual intercourse during the past 24 hours; Lack of abnormal uterine bleeding (AUB); Lack of frequent bacterial infections which are resistant to treatment; Not to be pregnant and lactation; Lack of vaginal douche in the past 48 hours; Lack of specific diseases such as Liver disease, diseases of the Central Nervous System, Diabetes, Immune deficiency, according to patient report; Non-use of broad-spectrum Antibiotics, Anti-prostaglandins, Hormone therapy and Immunosuppressive, Anticoagulant and drug abuse in recent months; No history of hypersensitivity to Metronidazole; The patient should have only BV not other types of Vaginitis. Exclusion Criteria: Possible sensitivity to the drug (vaginal cream of Jaft), which is not seen so far; Lack of application of vaginal cream (Jaft or Placebo) and oral Metronidazole or discontinuing treatment; Taking any medication affecting the vaginal cream including Alkaloid drugs; Taking any medication affecting the symptoms of BV including broad-spectrum Antibiotic to treat other infections in the patient; Unwillingness of patients to continue or to cooperate; People who are considered sick on the patient's clinical symptoms but their test results does not endorse BV.

#### Age

From **18 years** old to **45 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **168**

#### Randomization (investigator's opinion)

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 Shiraz University of Medical Sciences

##### Street address

Zand Street, Shiraz University of Medical Sciences  
Central building, Shiraz

##### City

Shiraz

##### Postal code

##### Approval date

2016-06-06, 1395/03/17

##### Ethics committee reference number

IR.SUMS.REC.1395.50

#### Health conditions studied

##### 1

#### Description of health condition studied

Bacterial Vaginosis

#### ICD-10 code

N-99

#### ICD-10 code description

Diseases of the Genitourinary system

#### Primary outcomes

##### 1

#### Description

Vaginal Discharge

#### Timepoint

Before and after the treatment of a week

#### Method of measurement

Through Smears of Vaginal discharges and Gram stained smears

#### Secondary outcomes

##### 1

#### Description

To reduce infectious factors such as bacteria and clinical symptoms

#### Timepoint

After a week of treatment

#### Method of measurement

Through the smears of vaginal discharges and gram stained slides

## Intervention groups

### 1

#### Description

The first intervention group, Oral tablet of Metronidazole 250 mg; 2 tablet; every 12 h, is given for 7 days.

#### Category

Treatment - Drugs

### 2

#### Description

The second intervention group vaginal cream of Jaft (one Applicator every night) is given coccurrent with oral tablet of Metronidazole 250mg, 2 tablets every 12 h.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

GYN Clinic of Shahid Faghihi Hospital

##### Full name of responsible person

Bahieh Namavar Jahromi

##### Street address

First floor of Shahid Fghihi Hospital, Zand street

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr.Masum Masumpur

##### Street address

7th floor, Central building of Shiraz University of Medical Science , Next to the Red Crescen , Zand Street , Shiraz

##### City

Shiraz

#### 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, Shiraz University of Medical Sciences

#### Proportion provided by this source

100

#### 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

School of Nursing and Midwifery, Shiraz University of Medical Sciences

##### Full name of responsible person

Zeinab Moshfeghy

##### Position

Masters of Midwifery

##### Other areas of specialty/work

##### Street address

Namazi squar, Shiraz

##### City

Shiraz

##### Postal code

##### Phone

+98 917 313 7561

##### Fax

##### Email

zmoshfeghy1385@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

School of Nursing and Midwifery, Shiraz University of Medical Sciences

##### Full name of responsible person

Zeinab Moshfeghi

##### Position

Masters of Midwifery

##### Other areas of specialty/work

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zmoshfeghy1385@yahoo.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

##### Full name of responsible person

Atefeh Zare

##### Position

Masters Student of Midwifery

**Other areas of specialty/work**

**Street address**

Shiraz

**City**

Shiraz

**Postal code**

**Phone**

**Fax**

**Email**

atp1990\_zare@yahoo.com

**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*