Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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 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 coccurent 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
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Person responsible for updating data

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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