

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The comparison of the effects of Micosin vaginal cream and Metronidazole vaginal gel on treatment of bacterial vaginosis

Protocol summary

Summary

The purpose of this randomized controlled trial is to compare the effect of vaginal garlic, thyme and Metronidazole creams in fungal treatment. The study will be performed on all women with vaginosis bacterial symptoms who refer to a clinic associated with Shiraz University of Medical Sciences. The researcher will first ask the patient to fill a consent form and then complete the initial questionnaire that contains questions about demographic and fertility. Also, the check list of vaginosis bacterial detection will filled by examination and interview. Vaginal discharge Amesel test will be sent to medicine laboratory for review. Finally, 120 women with positive Amsel test and positive secretion culture for vaginal bacterial and negative secretion culture for Candidiasis and Trichomonas will be chosen. Then, using a table of random numbers computed by randomized block permutation, they will be divided into two groups, A and B. Women in group A, will take medicine A and women in group B will take medicine B. A week after the treatment, all the patient will be interviewed and samples will be taken and the vaginal samples will be analyzed using Amsel subculture method to assess clinical improvement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062718187N2**
Registration date: **2014-07-22, 1393/04/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-07-22, 1393/04/31

Registrant information

Name

Sedighe Forouhari

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 987136474257

Email address

foruharis@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Shiraz University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effects of Micosin vaginal cream and Metronidazole vaginal gel on treatment of bacterial vaginosis

Public title

Effects of vaginal cream, Garlic, Thyme and Metronidazole in Bacterial vaginosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Those who are willing to cooperate;
Married women of reproductive age (18 to 44 years old);
Positive, Gram staining of bacterial vaginosis; Bacterial

vaginosis symptoms on clinical examination; Non-current use of anti-parasitic drugs, antibiotics, immunosuppressive drugs and vaginal medications during the past two weeks; Lack of abnormal uterine bleeding; Not having recurrent vaginitis (4 or more than 4 times a year) ;No pregnancy; No breastfeeding; No use douching frequently; No alcohol and anticoagulant coumarin; No cases of multiple sex partners; No getting certain diseases, such as liver disease, diseases of the central nervous system, blood Dyscrasia, diabetes, immune deficiency; No history of allergy to mint category and garlic taken orally or topically. Exclusion criteria: Sensitivity to the drug and non-drug use; taking any prescribed medications with conflicting effect with medicines in this study; taking any drug that affect vaginosis symptoms and treatment; lack of patients interest

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Shiraz University of Medical Sciences

Street address

Research Deputy, Shiraz University of Medical Science

City

Shiraz

Postal code

1978-71345

Approval date

2014-03-19, 1392/12/28

Ethics committee reference number

CT-92-6941

Health conditions studied**1****Description of health condition studied**

Vginosis Bacterial

ICD-10 code

N76.8

ICD-10 code description

Other specified inflammation of vagina and vulva

Primary outcomes**1****Description**

Treatment of bacterial vaginosis in the two groups (vaginal cream, garlic and thyme Vmtrvnydazvll)

Timepoint

One week after the end of treatment

Method of measurement

Czech List, examination, testing Amsel

Secondary outcomes

empty

Intervention groups**1****Description**

A 50-gram tube of vaginal cream, garlic and thyme in a week by the samples will be used for the treatment of bacterial vaginosis.

Category

Treatment - Drugs

2**Description**

0.75 mg vaginal gel metronidazol a week by the sample will be used for the treatment of bacterial vaginosis.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari Clinic in Shiraz

Full name of responsible person

Maryam Asadi, Student of Msc in Midwifery

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed basir hashemi

Street address

Technology and Research Office, Research Deputy ,
Shiraz University of Medical Science, Zand Street,
Shiraz

City

shize

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Council of 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**

Shiraz University of Medical Sciences

Full name of responsible person

Sedighe Forouhari

Position

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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