

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A comparison between the effect of vaginal probiotic capsules and the oral tablet of Metronidazol on combined bacterial and trichomonal vaginitis in selected gynecology clinics of Shiraz University of Medical Science, 1390

Protocol summary

Summary

The present study aims to compare the effects of vaginal probiotic capsules and the oral tablet of Metronidazole on combined bacterial and trichomonal vaginitis. This randomized, single blind study is conducted on 100 females suffering from combined bacterial and trichomonal vaginitis. The study subjects are divided into two groups of 50 through random allocation. The diagnosis criteria are wet smear and gram stain. For group 1, vaginal probiotic capsules are prescribed for 10 days, while for the second group, oral tablets of metronidazole are prescribed for 7 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711201548N3**

Registration date: **2012-05-07, 1391/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-07, 1391/02/18

Registrant information

Name

Khadijeh Abdali

Name of organization / entity

Fatemeh college of nursing and midwifery, Shiraz

University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4255

Email address

abdalikh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy for research of Shiraz university of medical sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effect of vaginal probiotic capsules and the oral tablet of Metronidazol on combined bacterial and trichomonal vaginitis in selected gynecology clinics of Shiraz University of Medical Science, 1390

Public title

A comparison between the effect of vaginal probiotic capsules and the oral tablet of Metronidazol on combined bacterial and trichomonal vaginitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria of the study: Non-pregnant, non-lactating, and non-smoker women who aged between 18 and 55, being married, being willing to participate in the research, being in the follicular phase of the menstrual

cycle, having signs of trichomoniasis on physical examination, having signs of bacterial vaginosis on physical examination, not having abnormal vaginal bleeding at the time of sampling, not having vaginal intercourse and douching during 48 hours prior to the study, not taking vaginal medication, such as creams, suppositories, and vaginal disinfectants in 48 hours before the study, not taking medication for treatment during the last 3 months, not suffering from specific diseases, such as liver, heart, and kidney diseases, diabetes, central nervous system diseases, blood discrasia, immune system defects, and known sexually transmitted diseases, not having used broad-spectrum antibiotics, anti-prostaglandins, hormone and immunosuppressive drugs, alcohol, and anticoagulation in recent months, no history of sensitivity to metronidazole tablets, not having vulvovaginitis four or more times during the year, and not having multiple sexual partners. Exclusion criteria of the study: Having allergy to the elements of the probiotic products which were used in the study, being considered unhealthy based on the clinical diagnosis, while having negative test results, and having allergy to the medication compounds used in the study.

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Medical Research Ethics Committee of Shiraz
University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

shiraz

Postal code**Approval date**

2011-12-01, 1390/09/10

Ethics committee reference number

CT-90-5809

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

Trichomonas vaginitis

ICD-10 code

A59

ICD-10 code description

Urogenital trichomoniasis

2**Description of health condition studied**

Trichomonas vaginitis

ICD-10 code

A59

ICD-10 code description

Urogenital trichomoniasis

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

Gram stain,wet smear and clinical signs

Timepoint

Before intervention,1week and 10 days after intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Side effects

Timepoint

7-10 days after intervention

Method of measurement

questionnaire

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

vaginal probiotic capsule,once daily until 10 day

Category

Treatment - Drugs

2**Description**

Control group: standard treatment with oral

metronidazole 250 mg tablet every 12 hours, 2 to 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinab (PBUH) Specialized hospital

Full name of responsible person

Street address

Zeinab (PBUH)Specialized hospital, Defae moghaddas Square

City

Shiraz

2

Recruitment center

Name of recruitment center

Martyr Faghihi Hospital

Full name of responsible person

Street address

Next to Medical School,Karim Khan Zand Blvd.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Hattam

Street address

Deputy for Research, seventh Floor, the central structure of Shiraz University of Medical Sciences, next to the Red Crescent, Zand Avenue

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy for Research 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

Fatemeh (PBUH) College of Nursing and Midwifery, Shiraz

Full name of responsible person

Khadijeh Abdali

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Medicine

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Khadijeh Abdali

Position

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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