

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of using vaginal probiotic supplementation on treatment results and vaginal colonization 2 and 6 month after treatment of bacterial vaginosis and Vulvovaginal Candidiasis

Protocol summary

Summary

The purpose of the study and design of the study : the effect of vaginal probiotic on lactobacilli cultures and treatment outcome in patients with bacterial vaginosis and Vulvovaginal Candidiasis, double-blind , placebo is. Inclusion criteria : aged 18 to 40 years ; Married ; nonpregnant ; willing to participate in research ; suffering from bacterial vaginosis or Vulvovaginal Candidiasis (according to the criteria of Amsel and culture test fungi) ; having menstrual natural ☐ nonsmokers ; not suffering from diseases such as liver disease heart , kidney, diabetes , Sbb system diseases , immune deficiency , sexually transmitted diseases, abnormal vaginal bleeding ; lack of non-use of broad-spectrum antibiotics , hormones (such as birth control pills) , alcohol , drugs anticoagulant and immunosuppressive drugs during the past month ; lack of sexual intercourse during the last 48 hours of non-use vaginal medicines within the last 48 hours last 48 hours ; lack of vaginal washings or not sensitive to clindamycin clotrimazole during pregnancy Exclusion Criteria : allergies symptoms, allergy to clindamycin or clotrimazole vaginal probiotic or placebo ; Getting pregnant sample selection: 140 patients eligible for the study , diagnosis and treatment of disease, and the random allocation of subjects to groups . Intervention of a vaginal probiotic group and the other group was given a placebo . Tracking people : Lactobacillus culture results before treatment , 2-5 days and one month after the probiotic or placebo groups are studied . Outcomes study : effect on cultured probiotic lactobacilli and treatment outcomes

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050617603N1**

Registration date: **2014-06-22, 1393/04/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-22, 1393/04/01

Registrant information

Name

Somaye Hooshyar

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1832 8996

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hooshyar_s@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Sciences

Expected recruitment start date

2014-04-20, 1393/01/31

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using vaginal probiotic supplementation on

treatment results and vaginal colonization 2 and 6 month after treatment of bacterial vaginosis and Vulvovaginal Candidiasis

Public title

Effect of vaginal probiotic on bacterial vaginosis and vaginal candidiasis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : aged 18 to 40 years ; Married ; nonpregnant ; willing to participate in research ; suffering from bacterial vaginosis or Vulvovaginal Candidiasis (according to the criteria of Amsel and culture test fungi) ; having menstrual natural ☐ nonsmokers ; not suffering from diseases such as liver disease heart , kidney, diabetes , Sbb system diseases , immune deficiency , sexually transmitted diseases, abnormal vaginal bleeding ; lack of non-use of broad-spectrum antibiotics , hormones (such as birth control pills) , alcohol , drugs anticoagulant and immunosuppressive drugs during the past month ; lack of sexual intercourse during the last 48 hours of non-use vaginal medicines within the last 48 hours last 48 hours ; lack of vaginal washings or not sensitive to clindamycin clotrimazole during pregnancy Exclusion Criteria : allergies symptoms, allergy to clindamycin or clotrimazole vaginal probiotic or placebo ; Getting pregnant

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: **140**

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

Shiraz University Of Medical Sciences

Street address

Nmazi squer

City

shiraz

Postal code

7174917787

Approval date

2014-04-26, 1393/02/06

Ethics committee reference number

CT_9362_6992

Health conditions studied

1

Description of health condition studied

vulvitis and vulvovaginal candida

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

2

Description of health condition studied

bacterial vaginosis

ICD-10 code

N76

ICD-10 code description

inflammation of vagina and vulva

Primary outcomes

1

Description

Cultivated candida

Timepoint

2-5 days after initial treatment,2-5 days after and one month after the use of probiotics or placebo

Method of measurement

Cultivate

2

Description

Amsel criteria

Timepoint

5-2 days after initial treatment,2-5 days after and one month after the use of probiotics or placebo

Method of measurement

Discharge, vaginal PH measurements,Whiff test, see clue cells under the microscope

3

Description

Cultures of vaginal lactobacilli

Timepoint

2-5days after initial treatment,2-5 days after and one month after the use of probiotics or placebo

Method of measurement

Cultures of vaginal lactobacilli

Secondary outcomes

1

Description

reacton to probiotics - clindamycin -clotrimazole

Timepoint

During the entire study

Method of measurement

The patient complained

Intervention groups

1

Description

Vaginal probiotic capsules containing Lactobacillus rhamnosus 10⁹ colony is known to be vaginally twice a day for seven days

Category

Treatment - Drugs

2

Description

Vaginal placebo capsule form twice a day for seven days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid rezaee clinic

Full name of responsible person

mrs hosein zadegan

Street address

valiasr squer .salman farsi BLV

City

shiraz

2

Recruitment center

Name of recruitment center

Azadegan clinic

Full name of responsible person

mrs nirumand hoseini

Street address

South Edalat BLV. Dolat BLV

City

shiraz

3

Recruitment center

Name of recruitment center

Hafez clinic

Full name of responsible person

mrs Eslami nasab

Street address

Ehsan squer

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. Gholam Reza Hatam

Street address

7th Flat, Central department of Shiraz University of Medical Sciences, 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

Fatemeh (PBUH) College of Nursing and Midwifery

Full name of responsible person

sara Azima

Position

Faculty Member, MSc in Midwifery

Other areas of specialty/work

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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