Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 culturesand 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 , Sbby 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

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Name of organization / entity

Shiraz University Of Medical Sciences

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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 , Sbby 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 vaginosise
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 10 ^ 9 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
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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