

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of the Lactofem oral probiotic Capsule on the Lactobacilli colonization and some parameters of the vaginal health in women 18-55 year's old admitted to the Health Centers of Shiraz University Medical Science in 2015.

Protocol summary

Summary

The purpose of the study and designing of the study performance: The effect of oral Lactofem probiotic capsule on lactobacillus colonization and some vaginal health indices during the age of 18 up to 55 years. This study has been double-blind and placebo. Inclusion criteria: The age 18-55 years; married; nonpregnant women; willing to participate in study; having natural menstrual cycles; nonsmokers; Nugent score = 4-6; pH >4.5; clinically, the samples not suffered any vaginitis; not suffered from such disease as liver, heart, kidney, diabetes, nervous system ailments, immunodeficiency, sexually transmitted illnesses; non abnormal vaginal bleedings. Exclusion criteria: pregnancy occurrence during the study; the use of vast spectrum antibiotics, hormonal drugs, alcohol, anticoagulation drugs and the recent month immunosuppressive; infection existence; ulcers, injury and abnormal secretions in the vulve, vagina and cervix examinations; sensitivity symptoms against oral probiotic; suspension with going on the study participation. Target sample size: selection of eighty individuals of the qualified study community. Random allocation of subjects into two groups. Intervention: oral probiotic is given to a group and placebo to another one. Tracking people: vaginal pH measurement, lactobacillus culture and assigning of Nugent score respectively after 10, 30, 60 and 70 days of consuming probiotic or placebo in two study groups. Outcome study: the effect of oral probiotic on the measured pH, lactobacillus culture and Nugent score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062322892N1**

Registration date: **2015-09-04, 1394/06/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-04, 1394/06/13

Registrant information

Name

Seyedeh Zohreh Balaghi

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

7th Floor, Vice chancellor for Research, Shiraz University of Medical Sciences, Central department of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran. Postal Code: 7174917787, Tel: 00987132122389

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the Lactofem oral probiotic Capsule on the Lactobacilli colonization and some parameters of the vaginal health in women 18-55 year's old admitted to the Health Centers of Shiraz University Medical Science in 2015.

Public title

The effect of the oral probiotic on some parameters of the vaginal health

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The age 18-55 years; married; nonpregnant women; willing to participate in study; having natural menstrual cycles; nonsmokers; Nugent score = 4-6; pH >4.5; clinically, the samples not suffered any vaginitis; not suffered from such disease as liver, heart, kidney, diabetes, nervous system ailments, immunodeficiency, sexually transmitted illnesses; non-abnormal vaginal bleedings
Exit criteria: pregnancy occurrence during the study; the use of vast spectrum antibiotics, hormonal drugs, alcohol, anticoagulation drugs and the recent month immunosuppressive; infection existence; ulcers, injury and abnormal secretions in the vulva, vagina and cervix examinations; sensitivity symptoms against oral probiotic; suspension with going on the study participation

Age

From **18 years** old to **54 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Science

Street address

Shiraz University of Medical Science, Zand street, Shiraz

City

Shiraz

Postal code

7134814336

Approval date

2015-06-21, 1394/03/31

Ethics committee reference number

IR.SUMS.REC.1394.47

Health conditions studied

1

Description of health condition studied

Vaginal health

ICD-10 code

T19.2

ICD-10 code description

Foreign body in vulva and vagina

Primary outcomes

1

Description

Vaginal pH

Timepoint

respectively after 10, 30, 60 and 70 days of consuming probiotic or placebo in two study groups

Method of measurement

Test strip Merck Germany

2

Description

Nugent score

Timepoint

respectively after 10, 30, 60 and 70 days of consuming probiotic or placebo in two study groups

Method of measurement

Take smear from vagina with a cotton swab and make a direct smear on a microscope slide . In the laboratory the smears were stained and observed under the microscope to estimate nugent score.

3

Description

lactobacillus colonization of vagina

Timepoint

respectively after 10, 30, 60 and 70 days of consuming probiotic or placebo in two study groups

Method of measurement

Coun Lactobacillus

Secondary outcomes

empty

Intervention groups

1

Description

The oral probiotic capsule which contains a large amount of probiotic such as L. Acidophilus, L. plantarum, L. fermentum and L. gasseri are given one 500 milligram capsule during sixty days.

Category

Treatment - Drugs

2

Description

Placebo capsule which are orally given one capsule per day during 60 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nader Kazemi Clinic

Full name of responsible person

Mrs Vafaee

Street address

Valiasr Square

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th Flat, Central Department of Shiraz University of Medical Sciences, Zand Street

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