

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of vaginal probiotic products in eliminating Human Papillomavirus in women with HPV

Protocol summary

Study aim

Investigating the effect of vaginal probiotic products in eliminating HPV virus in women

Design

This is a non-blinded randomized clinical trial with a parallel design and a control group. This randomized, phase 2-3 study will be conducted on at least 54 women with human papillomavirus. A simple random method is used for randomization and the participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted at Imam Reza Hospital in Kermanshah, is non-blinded. First, a PCR test is performed for the participants in the laboratory by the resident, and high-risk patients with a positive HPV test result are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Age 21-65 years; Married; Being in the follicular period of the menstrual cycle; Not having intercourse and not washing the vagina in the last 48 hours Exclusion criteria: Pregnant, lactating, and smoking women; People who are considered sick based on clinical diagnosis but whose test results are negative; Using vaginal drugs such as creams, suppositories, and vaginal disinfectants in the last 48 hours; Suffering from certain diseases such as liver, heart, kidney disease, diabetes, central nervous system diseases, blood dyscrasias, immune system defects and known sexually transmitted diseases; Use of broad-spectrum antibiotics, antiprostaglandins, hormonal and immunosuppressive drugs, alcohol, and anticoagulant drugs during the last month.

Intervention groups

The intervention group will receive vaginal probiotic capsules (with the trade name Lacto vag, manufactured by the American Food and Drug Company, a pack of 30), two vaginal capsules per week for 6 months. The control group will receive routine treatment.

Main outcome variables

wet smear

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N200**

Registration date: **2023-05-20, 1402/02/30**

Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**

Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vaginal probiotic products in eliminating Human Papillomavirus in women with HPV

Public title

The effect of vaginal probiotic products in eliminating Human Papillomavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Age 21-65 years married being in the follicular period of the menstrual cycle; Not having intercourse and not washing the vagina in the last 48 hours

Exclusion criteria:

Pregnant, lactating and smoking women People who are considered sick based on clinical diagnosis but whose test results are negative Using vaginal drugs such as creams, suppositories and vaginal disinfectants in the last 48 hours Suffering from certain diseases such as liver, heart, kidney disease, diabetes, central nervous system diseases, blood dyscrasias, immune system defects and known sexually transmitted diseases. Use of broad-spectrum antibiotics, antiprostaglandins, hormonal and immunosuppressive drugs, alcohol, and anticoagulant drugs during the last month

Age

From **21 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned to the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned to the second intervention group.

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 of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.KUMS.MED.REC.1402.020

Health conditions studied

1

Description of health condition studied

human papillomavirus (HPV)

ICD-10 code

B97.7

ICD-10 code description

Papillomavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

wet smear

Timepoint

6 months after the start of the study

Method of measurement

Pap smear test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive vaginal probiotic capsules (with the trade name Lacto vag, manufactured by the American Food and Drug Company, a pack of 30), two vaginal capsules per week for 6 months

Category

Treatment - Drugs

2

Description

The control group will receive routine treatment

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. saba Najafi

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Cyrus Jalili

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Vice Chancellor for Research Affairs, Kermanshah
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Saba Najafi

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Maryam Zangeneh

Position

Member of the faculty of Kermanshah University of
Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available