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

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Iran (Islamic Republic of)

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+98 83 1821 4653

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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
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Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Dr. Saba Najafi
Position
Resident of Obstetrics and Gynecology
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Person responsible for updating data

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Medical doctor

Other areas of specialty/work
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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