Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Efficacy and safety of vaginal probiotic suppository plus cryotherapy in comparison with cryotherapy monotherapy in improving genital warts

Protocol summary

Study aim
Evaluation of the effect of vaginal probiotics on the improvement of genital warts lesions in women

Design
A phase 1/2 controlled clinical trial with parallel groups, randomized, conducted on 20 patients. Randomization was performed using Microsoft Excel.

Settings and conduct
In this randomized pilot study, female patients with genital wart lesions who presented to the cryotherapy clinic of Razi Hospital will be enrolled. All demographic data will be collected. Both groups will undergo four cryotherapy sessions, each three weeks. The treatment group will receive three 10-day courses (one per month) of Provaage vaginal probiotic suppositories, except during menstrual bleeding. The suppository will be applied nightly using an applicator, and patients will remain lying down for 10 minutes to improve absorption. Warts will be evaluated at each session by the number and size of lesions. Quality of life will be assessed using the Dermatologic Life Quality Assessment questionnaire, and clearance of lesions at the final treatment session will be evaluated by the Physician Global Assessment (PGA). One month after the final session, patients will be reassessed for recurrence of lesions

Participants/Inclusion and exclusion criteria
In this study, 20 women between 18 and 50 years of age with genital warts are enrolled. Those with a history of immunodeficiency diseases, pregnancy and breastfeeding, high-grade HPV infection, precancerous or cancerous lesions, or no history of sexual intercourse are excluded.

Intervention groups
The treatment group (four cryotherapy sessions plus three 10-day courses of vaginal probiotic suppositories) and the control group (four cryotherapy sessions).

Main outcome variables
Physician Global Assessment; Dermatology Quality Life Index; Number of lesions; Size of lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251112067973N1**
Registration date: **2026-06-29, 1405/04/08**
Registration timing: **prospective**

Last update: **2026-06-29, 1405/04/08**
Update count: **0**

Registration date
2026-06-29, 1405/04/08

Registrant information

Name
Yekta Ghane

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5557 5141

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yektaghanemd@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-02, 1405/05/11

Expected recruitment end date
2027-01-31, 1405/11/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Efficacy and safety of vaginal probiotic suppository plus cryotherapy in comparison with cryotherapy monotherapy in improving genital warts

Public title
Efficacy and safety of vaginal probiotic suppository plus cryotherapy in comparison with cryotherapy monotherapy in improving genital warts
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
20 women with genital warts
Exclusion criteria:
History of immunodeficiency Pregnancy and/or Breastfeeding High-grade HPV Precancerous and Cancerous Lesions No history of intercourse
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using a block randomization method with a block size of 4 and a 1:1 allocation ratio. The allocation sequence will be generated by an independent statistician, separate from the treatment team, using Excel software. Participants will be assigned to groups via sequentially numbered, sealed envelopes (SNOSE), which will be opened only after definitive enrollment of each patient by the responsible investigator. This ensures that allocation concealment is maintained and that the assignment process is independent of enrollment.
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 Immunology, Asthma and Allergy Research Institute
Street address
Tehran University of Medical Sciences, Poursina St, Qods St, Enqelab St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1461884513
Approval date
2025-05-11, 1404/02/21
Ethics committee reference number
IR.TUMS.IAARI.REC.1404.002

Health conditions studied

1

Description of health condition studied
Genital wart
ICD-10 code
A63.0
ICD-10 code description
Anogenital (venereal) warts

Primary outcomes

1

Description
Total number and the size of the lesions
Timepoint
Every 3 weeks
Method of measurement
Counting the lesions and ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Patients in this group will receive 4 sessions of cryotherapy every three weeks. Each session will be performed by a board-certified dermatologist using a liquid nitrogen spray device (Model C-609, Azin Co., Iran). Liquid nitrogen at −196°C will be applied as a direct spray for 2 seconds per lesion per session. In addition, patients will receive 3 consecutive 10-day courses (one per month) of Provage vaginal probiotic suppositories (Gostaresh Milad Pharmed Co., Iran). Each 500 mg capsule contains Lactobacillus rhamnosus and Lactobacillus gasseri (>500 million CFU per strain). The suppository is self-administered vaginally each night before sleep using an applicator; patients remain supine for 10 minutes after insertion to facilitate absorption. Use is suspended during menstrual bleeding.
Category
Treatment - Other

2

Description
Patients in this group will receive 4 sessions of cryotherapy every three weeks, performed by the same board-certified dermatologist using the same device and protocol as described above. No additional pharmacological intervention will be administered.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Zeynab Aryanian
Street address
Razi Hospital- Vahdate-e-eslami St, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
6th Floor, Vice Presidency of Research and Technology Central Administration Building, Tehran University Keshavarz Blvd., at the corner of Qods St. Tehran, Iran
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Yekta Ghane
Position
Post-doctoral research fellow
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Autoimmune Bullous Diseases Research Center, Razi Hospital, Razi Alley, Vahdat-e Eslami St., below Vahdat-e Eslami Sq., Tehran, Iran
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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long

Starting after publication

To whom data/document is available

Data is available upon request

Under which criteria data/document could be used

Requests are reviewed on a case-by-case (individual) basis.

From where data/document is obtainable

Via email address: Yektaghanemd@gmail.com

What processes are involved for a request to access data/document

Submit your request online via email. They must reply within 10 working days (usually 3–20 days in practice). Receive the file digitally or (rarely) in physical form. Most simple requests take 1–3 weeks.

Comments