Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effectiveness of topical vitamin D3 and cryotherapy in comparison with cryotherapy in treating anogenital warts

Protocol summary

Study aim
The study aims to assess the impact of vitamin D ointment on anogenital wart lesions as a new therapeutic method and compare it with common treatment (cryotherapy). Due to the lack of reported side effects, we will also report the resulting side effects.

Design
A single-blinded, randomized trial with two parallel arms that will be performed with 30 patients in each arm. Random allocation software was used to assign patients randomly.

Settings and conduct
The study is conducted in Razi Hospital, located in Tehran. Referred patients are first examined, and will be included in the study if they are eligible. The included patients are unaware of the therapy (vitamin D ointment or vaseline). Both medications are given in the same containers to perform proper blinding.

Participants/Inclusion and exclusion criteria
Age over 18, more than 2 warts in anogenital area, willingness to participate, absence of inflammatory skin disease and rheumatological disease, absence of liver and kidney disease, absence of allergy to vitamin D, absence of malignancy, diabetes and immunodeficiency, absence of pregnancy and breastfeeding

Intervention groups
There are two intervention groups in this study. The first group will receive cryotherapy plus vitamin D ointment and the second group will receive cryotherapy plus placebo (vaseline). Cryotherapy sessions will be performed at three-week intervals, and the patients of both groups will utilize the topical treatment twice a day. The study duration is three months.

Main outcome variables
Measuring the number and size of genital warts

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230124057201N4**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date
2023-11-25, 1402/09/04

Registrant information

Name
Zeinab aryanian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 5563 0853
Email address
z_aryanian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of topical vitamin D3 and cryotherapy in comparison with cryotherapy in treating anogenital warts

Public title
Investigating the impact of topical vitamin D on anogenital warts
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of HPV Patients with more than two genital warts in genitalia (perinea, groin, anus) Age more than 18 Willingness to participate in the study
Exclusion criteria:
Inflammatory skin disease Rheumatological disease Malignancy Kidney and liver disease Eczema Diabetes mellitus Previous history of allergy to vitamin D Acquired immunodeficiency Pregnancy and lactation
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly assigned to cryotherapy and placebo or cryotherapy and drug via block randomization with blocks of four. Random allocation software was used to make a list of random numbers. If the number made by software was between 0 and 4, the patients belonged to the placebo group, and if the number was between 5 and 9, the patients were placed in the drug group. The process was repeated until all the eligible patients were included in the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients enrolled in the study are not aware of the received medicine (placebo or vitamin D ointment) that is given with cryotherapy. To avoid identifying the type of drug, placebo (vaseline) and drug (vitamin D ointment) are given in the same containers previously prepared.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of tehtan university of medical science
Street address
Tehran University of medical sience, ghods street,keshavarz boulevard
City
Tehtan
Province
Tehran
Postal code
1417613151
Approval date
2023-11-12, 1402/08/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.436

Health conditions studied

1

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

Primary outcomes

1

Description
Measuring size and number of anogenital warts
Timepoint
Baseline visit, then every three week up to four sessions
Method of measurement
Lesion count, surgical grading ruler

Secondary outcomes

1

Description
Qualitative evaluation of response to treatment (complete response, partial response 50-99%, no response less than 50%)
Timepoint
Last treatment session
Method of measurement
Qualitative

2

Description
Patient's satisfaction
Timepoint
Last treatment session
Method of measurement

Qualitative evaluation (Very satisfied, Satisfied, Somehow satisfied, Unsatisfied)

Intervention groups

1

Description
Intervention group: Patients in addition to four cryotherapy sessions will use vitamin D ointment (calciderm) twice a day. the interventions will continue for three months.
Category
Treatment - Drugs

2

Description
Control group: In this group, in addition to four cryotherapy sessions, patients will use a placebo (Vaseline) twice a day. the intervention will also be three months in this group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Dr.Zeinab Aryanian
Street address
Razi hospital, Vahdat Eslami Square,Vahdat Eslami Avenue,Tehran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0553
Email
razihospital@sina.tums.ac.ir
Web page address
https://razihos.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Research and technology affairs, central building of tehran university of medical science, ghods street, keshavarz boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3102
Email
itcenter@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
Dr. Zeinab Aryanian
Position
Assisstant professor
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Razi hospital, Vahdat Eslami Square, Vahdat Eslami Avenue, Tehran
City
Tehran
Province
Tehran
Postal code
1199663911
Phone
+98 21 5563 0553
Email
z_aryanian@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Dr. Zeinab Aryanian

Position
Assisstant professor

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
Razi hospital, Vahdat Eslami Square, Vahdat Eslami Avenue, Tehran

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

Email
z_aryanian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sama Heidari

Position
General physician

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
Razi hospital, Vahdat Eslami Square, Vahdat Eslami Avenue, Tehran

City
Tehran

Province
Tehran

Postal code
1199663911

Phone
+98 21 5563 0553

Email
sama.h9473@gmail.com

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
Since all the information obtained from patients is confidential, the data will not be published.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The study protocol will be accessible instantly after publication.

When the data will become available and for how long
Immediately after publishing the study results, access to the protocol is possible.

To whom data/document is available
Academic researchers are eligible to receive.

Under which criteria data/document could be used
It is acceptable to use the data only to obtain ideas from the protocol or extract the results.

From where data/document is obtainable
Scientific responsible in the study/ correspondence

What processes are involved for a request to access data/document
After requesting from the scientific responsible, the qualified data (such as results) will be sent.

Comments