

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 (perineal, 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 science, 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 (calcidem) 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

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razihospital@sina.tums.ac.ir

Web page address

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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,

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1417653761

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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

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

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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