Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of 5% potassium hydroxide solution versus cryotherapy on treatment of anogenital warts in men: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of 5% potassium hydroxide solution versus cryotherapy on treatment of anogenital warts in men

Design
This is a randomized clinical trial, phase III, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible men with anogenital warts referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 75 years, Male anogenital warts, Exclusion criteria: Active skin wound or infection at the treatment site, Coagulation disorders, Immunodeficiency disorder, Any treatment for warts in the last 2 months, Cold intolerance, History of seizures

Intervention groups
Intervention group: Rubbing topical 5% potassium hydroxide solution (manufactured by Avsina Co.)on the wart twice and then every two weeks up to 4 times
Control group: Cryotherapy using liquid nitrogen (manufactured by Pishidad Gas Industrial Group) for 20 seconds on the wart twice and then every two weeks up to 4 times

Main outcome variables
Primary outcome: Wart diameter Secondary outcome: Side effects (pain, itching, burning, erythema, blister, scar, hypopigmentation, hyperpigmentation)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N394**
Registration date: **2021-05-14, 1400/02/24**
Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**
Update count: **0**

Registration date
2021-05-14, 1400/02/24

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2022-10-22, 1401/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of 5% potassium hydroxide solution versus cryotherapy on treatment of anogenital warts in men: a randomized clinical trial

Public title
Effect of 5% potassium hydroxide solution versus liquid nitrogen on treatment of anogenital warts in men
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 75 years, Male anogenital warts,
Exclusion criteria:
Active skin wound or infection at the treatment site, Coagulation disorders, Immunodeficiency disorder, Any treatment for warts in the last 2 months, Cold intolerance, History of seizures
Age
From **18 years** old to **75 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2021-05-01, 1400/02/11
Ethics committee reference number
IR.UMSHA.REC.1400.115

Health conditions studied

1

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

Primary outcomes

1

Description
Wart diameter
Timepoint
Before the intervention and every 2 weeks after intervention for 4 times
Method of measurement
With clinical examination and imaging of skin lesions

Secondary outcomes

1

Description
Side effects (pain, itching, burning, erythema, blister, scar, hypopigmentation, hyperpigmentation)
Timepoint
Every 2 weeks after the intervention for 4 times
Method of measurement
With clinical examination

Intervention groups

1

Description
Intervention group: Rubbing topical 5% potassium hydroxide solution (manufactured by Avsina Co.)on the wart twice and then every two weeks up to 4 times
Category
Treatment - Drugs

2

Description
Control group: Cryotherapy using liquid nitrogen (manufactured by Pishidad Gas Industrial Group) for 20

seconds on the wart twice and then every two weeks up to 4 times

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr Esmaeil Esmaeili

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Esmaeil Esmaeili

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Name of organization / entity

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Dermatologist

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr. Jalal Poorolajal

Position
Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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