

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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.

**City**

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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

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Bahareh Ebrahimi

**Position**

Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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## Person responsible for updating data

poorolajal@umsha.ac.ir

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**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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**Email**

## 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