

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of extra genital warts: a single-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of extra genital warts

##### Design

This is a single-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

##### Settings and conduct

This study will be performed in the Sina Hospital in Hamadan city on 110 eligible patients with extra genital warts. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 8 to 65 years Extra genital warts  
Exclusion criteria: Pregnancy or breastfeeding Ulcers, infections, or active skin disease at the treatment site  
Coagulation disorder Immune system defect Treatment of warts in the last month Intolerance to cold

##### Intervention groups

Intervention group: Placing the applicator dipped in topical solution hydrogen peroxide 40% on the wart twice for 20 seconds each time and repeating it weekly for a maximum of 8 weeks. Control group: Placing the applicator dipped in liquid nitrogen on the wart twice for 20 seconds each time and repeating it weekly up to a maximum of 8 weeks.

##### Main outcome variables

Primary outcome: Improvement of wart lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N438**

Registration date: **2022-08-15, 1401/05/24**

Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**

Update count: **0**

##### Registration date

2022-08-15, 1401/05/24

##### 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

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-02-19, 1401/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of topical solution hydrogen peroxide 40% versus

cryotherapy on the treatment of extra genital warts: a single-blind randomized clinical trial

#### Public title

Effect of topical solution hydrogen peroxide 40% versus cryotherapy on the treatment of extra genital warts

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age of 8 to 65 years Extra genital warts

##### Exclusion criteria:

Pregnancy or breastfeeding Ulcers, infections, or active skin disease at the treatment site Coagulation disorder Immune system defect Treatment of warts in the last month Intolerance to cold

#### Age

From **8 years** old to **65 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Outcome assessor

#### Sample size

Target sample size: **110**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind.

#### 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

2022-06-25, 1401/04/04

#### Ethics committee reference number

IR.UMSHA.REC.1401.324

### Health conditions studied

#### 1

##### Description of health condition studied

Extra genital warts

##### ICD-10 code

A63.0

##### ICD-10 code description

Anogenital (venereal) warts

### Primary outcomes

#### 1

##### Description

Improvement of wart lesions

##### Timepoint

Weekly for 8 weeks

##### Method of measurement

Through clinical examination

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Placing the applicator dipped in topical solution hydrogen peroxide 40% on the wart twice for 20 seconds each time and repeating it weekly for a maximum of 8 weeks.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: Placing the applicator dipped in liquid nitrogen on the wart twice for 20 seconds each time and repeating it weekly up to a maximum of 8 weeks.

##### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Sina Hospital in Hamadan city

**Full name of responsible person**

Dr. Shabnam Kooshk

**Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

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**Province**

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**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

shabnamkooshk@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

**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. Shabnam Kooshk

**Position**

Resident of Dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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

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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. Mohammad Jamshidi

**Position**

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**

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**

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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