

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)

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+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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6517838695

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+98 81 3838 0572

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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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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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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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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