Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of therapeutic effects and complications of 40% topical hydrogen peroxide solution with cryotherapy in genital wart lesions

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of 40% topical hydrogen peroxide solution in patients with genital wart lesions.

Design

Randomized clinical trial with control group, with parallel groups, without blinding, , phase 3 on 40 patients. For randomization, closed envelopes with A and B written inside them were used.

Settings and conduct

This study was performed in Sina Hospital, Tabriz, dermatology ward, and there is no blinding. Patients in the intervention and control groups will be randomly evaluated using Sealed envelopes.

Participants/Inclusion and exclusion criteria

Patients over 18 years old ,having at least 1 genital wart ,Not using previous treatment, and consent to participate in the study will be included in the study. Pregnant and lactating women, patients who are afraid to use the treatment will be excluded from the study.

Intervention groups

In the intervention group, only local hydrogen peroxide solution (40% by volume) will be applied in one or two of their wart lesions and it will be kept for 20 seconds with rotating movements and pressure on the lesion. In each session, this cycle will be repeated 4 times, which will be 80 seconds in total.For other warts in this group, the standard treatment of genital warts (cryotherapy) will be performed. in control group only cryotherapy will be used.Medication (for the intervention group) and cryotherapy (for the control group) will be done in the first visit, the visit 3 weeks later, and the visit 6 weeks later, and each time the patients will be examined in terms of the effects of the treatment, efficacy and side effects of receiving the medicine And In the visit 8 weeks later, the patients will only be examined in terms of the effects of the treatment and the side effects of taking the medicine and will not receive any intervention.

Main outcome variables

Diameter and Height of warts. probable side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120524009844N10**
Registration date: **2023-04-13, 1402/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-13, 1402/01/24**
Update count: **0**

Registration date

2023-04-13, 1402/01/24

Registrant information

Name

Mehdi Amirnia

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-05, 1401/12/14

Expected recruitment end date

2023-05-04, 1402/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of therapeutic effects and complications of 40% topical hydrogen peroxide solution with cryotherapy in genital wart lesions

Public title
Therapeutic effects and complications of hydrogen peroxide solution in genital warts

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having at least 1 genital wart Satisfaction with the study Age above 18 years
Exclusion criteria:
Pregnant and beast feeder women Patients who are afraid to use treatment

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization will be carried out on an individual basis by RandList software. The selection of patients will be based on sealed envelopes that be written A and B inside them. 40 envelopes will be prepared in two groups. After entering the clinic and before the visit, patients will receive the envelope from the secretary and hand it over to the physician.

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 Tabriz University of Medical Sciences
Street address
Sina Hospital, Azadi street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5163639888

Approval date
2023-02-06, 1401/11/17

Ethics committee reference number
IR.TBZMED.REC.1401.1005

Health conditions studied

1

Description of health condition studied
Genital wart

ICD-10 code
B07.8

ICD-10 code description
Other viral warts

Primary outcomes

1

Description
Diameter of warts

Timepoint
Weeks 0,3,6 and 8 after treatment

Method of measurement
Clinical examination and Measure by ruler

2

Description
Height of warts

Timepoint
Weeks 0,3,6 and 8 after treatment

Method of measurement
Clinical examination and measurement with caliper

3

Description
Probable side effects

Timepoint
Weeks 0,3,6 and 8 after treatment

Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: In each patient, after examining the

warts and relative matching according to the size and location, local 40% hydrogen peroxide solution will be used on one or two genital wart lesions in the intervention group. this solution will be used on the lesion to cover the entire surface of the lesion And then it will be kept for 20 seconds with rotating movements and pressure on the lesion. In each session, this cycle will be repeated 4 times, which will be 80 seconds in total. This intervention will be done at the beginning of the study and will be repeated in the third and sixth weeks if there is no improvement.For their other lesions, only standard genital wart treatment (cryotherapy) will be used.in the visit 8 weeks later, the patients will be evaluated only in terms of The effects of treatment, efficiency and side effects of receiving the drug have been checked and they will not receive intervention.

Category

Treatment - Other

2

Description

Control group: The Control group will be treated with liquid nitrogen cryotherapy, using spray 1-2 cm away from the lesion for 20-30 seconds, depending on the size of the wart to create a white halo around the wart as much as 1 mm. Cryotherapy (for the control group) will be performed in the first visit, the visit 3 weeks later and the visit 6 weeks later, and each time the patients will be examined in terms of the effects of the treatment, efficiency and side effects of the treatment, and in the visit 8 weeks later, the patients will be evaluated only in terms of The effects of treatment, efficiency and side effects of receiving the drug have been checked and they will not receive intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Mehdi Amirnia

Street address

Azadi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Amirnia

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Dr. Mehdi Amirnia

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long
Access to study data after publication of the result is available in the journal.

To whom data/document is available
Anyone interested in using the data can access the study data.

Under which criteria data/document could be used
Study data can be used for comparison with other results.

From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.

Comments