

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the topical effect of 5% potassium hydroxide solution with cryotherapy in the treatment of patients with genital warts

Protocol summary

Study aim

Comparison of the local effect of 5%KOH solution with cryotherapy in the treatment of patients with genital warts

Design

A clinical trial study investigating the effect of 5% KOH solution compared to cryotherapy as a control group will be conducted on 98 patients (49 people in the intervention group and 49 people in the control group) and for randomization the blocking method will be used

Settings and conduct

This study will be conducted in the dermatology clinic of Imam Reza Hospital in Mashhad. The selected patients were randomly divided into two groups, and the first group included 49 patients treated with 5% KOH solution daily locally using a swap, and the second group included 49 patients treated with cryotherapy. Patients will be visited before starting the treatment and their age, sex, number of lesions will be checked and recorded. Then, patients are visited at intervals of 4 weeks from the beginning of treatment to 12 weeks, and the number of lesions, duration of complete recovery (based on days) and skin complications including itching and pain (using a score of 1 to 10) and Hyperpigmentation or hypopigmentation, erosion and ulcers (occurrence or absence of complications) will be checked and recorded. 8 weeks after complete recovery, patients will be visited for recurrence.

Participants/Inclusion and exclusion criteria

Entry condition: patients with external genital warts whose number of lesions is less than 10 and the size of lesions is less than 1 cm. Conditions of non-entry: pregnant and lactating women, age less than three years, sensitivity to potassium hydroxide solution, warts larger than 1 cm or more than 10

Intervention groups

Daily treatment with 5% KOH solution locally

Main outcome variables

Number of scraps Time to complete recovery Skin

complications including itching, pain, hyper or hypopigmentation, erosion and ulcers Recurrence of lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230417057941N1**

Registration date: **2023-05-24, 1402/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-24, 1402/03/03**

Update count: **0**

Registration date

2023-05-24, 1402/03/03

Registrant information

Name

Fateme Javame Ghazvini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 8073

Email address

javamef991@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the topical effect of 5% potassium hydroxide solution with cryotherapy in the treatment of patients with genital warts

Public title
Comparison of the topical effect of 5% potassium hydroxide solution with cryotherapy in the treatment of patients with genital warts

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with external genital warts whose number of lesions is less than 10 and the size of lesions is less than 1 cm
Exclusion criteria:

Age
From 3 years old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: 98

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done in a block method with sealed envelopes

Blinding (investigator's opinion)
Double blinded

Blinding description
Considering that the treatment methods of the intervention group and the control group are completely different, therefore, only the researchers and the outcome evaluators and the analyzers can be kept blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences-Educational, Research and Treatment Center

Street address
Daneshgah Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9177154088

Approval date
2022-12-19, 1401/09/28

Ethics committee reference number
IR.MUMS.IRH.REC.1401.040

Health conditions studied

1

Description of health condition studied

Genital wart

ICD-10 code

A63.0

ICD-10 code description

Other predominantly sexually transmitted diseases, not elsewhere classifiedExcl.:molluscum contagiosum (B08.1)papilloma of cervix (D26.0)A63.0Anogenital (venereal) wartsA63.8Other specified predominantly sexually transmitted diseases

Primary outcomes

1

Description

Response to treatment: The ratio of the number of fully treated patients divided by the total number of patients in that group multiplied by 100

Timepoint

before starting treatment and at four-week intervals for a maximum of 12 weeks

Method of measurement

کاهش تعداد ضایعات به وسیله مشاهده محقق
Reducing the number of wastes by observing the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Treatment with 5% KOH solution, prepared by a pharmacist colleague in the Faculty of Pharmacy, is applied topically on the wart lesions using a swab by the patient until the lesions heal (for a maximum of 12 weeks)

Category

Treatment - Drugs

2

Description

Control group:Treatment with cryotherapy (liquid nitrogen) with 5-20 cycles every 2 weeks is performed by the doctor until the lesions heal (for a maximum of 12 weeks).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Fateme Javame

Street address

Dermatology clinic of Imam Reza hospital, Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9177154088

Phone

+98 51 3879 8073

Email

Javamef991@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayour

Street address

Danesh va salamat town , Fakoori Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177154088

Phone

+98 51 3879 8073

Email

Javamef991@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatame Javame

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 72 , Forghani 15 , Piroozi 26

City

Mashhad

Province

Razavi Khorasan

Postal code

9177154088

Phone

+98 51 3879 8073

Email

Javamef991@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatame Javame

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 72 , Forghani 15 , Piroozi 26

City

Mashhad

Province

Razavi Khorasan

Postal code

9177154088

Phone

+98 51 3879 8073

Email

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatame Javame

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 72 , Forghani 15 , Piroozi 26

City

Mashhad

Province

Razavi Khorasan

Postal code

9177154088

Phone

+98 51 3879 8073

Email

Javamef991@mums.ac.ir

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

Yes - There is 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

All data can be shared

When the data will become available and for how long

since 2024

To whom data/document is available

Medical and health researchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

To the researchers of this research

What processes are involved for a request to access data/document

To be sent to researchers first

Comments