

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effects of topical betamethasone valerate on post-cryotherapy inflammation in cutaneous wart treatment

Protocol summary

Study aim

Effect of topical Betamethasone ointment on inflammation after Cryotherapy in the treatment of skin wart

Design

Clinical trial with control group, double-blind, not randomized

Settings and conduct

The lesions are treated with cryotherapy on both sides of the body so that they extend up to 2 mm around the lesion. Topical betamethasone is then applied to the lesions on one side after cryotherapy, and the opposite side of the placebo ointment is applied to a tube of the same shape, size, and color. Also, the researcher does not know the type of ointment. The site of the operation is in Bouali Hospital of Sari city, patients refer to a dermatology clinic

Participants/Inclusion and exclusion criteria

Entry requirement 1. Patients with skin wart who have been diagnosed clinically or pathologically by a dermatologist and have cryotherapy indications 2. Patients over 2 years of age 3. Have a conscious desire to enter the study 4. the maximum number of warts is up to 20 No entry condition 1. Children under 2 years of age, pregnant and lactating women 2. People treated with systemic medications that interfere with wound healing or taking immunosuppressive drugs 3. Patients who have contraindications for cryotherapy 4. Patients who don't want to participate in the study 5. Patients who have used topical medications other than emollients in the past month 6. People who are allergic to betamethasone or topical steroids 7. Patients with impaired wound healing, such as diabetes 8. Distributed and resistant warts that need other treatment

Intervention groups

In the first group, lesions on a limb, betamethasone, were used In the second group, lesions on other organs placebo were used

Main outcome variables

Symptoms include pain, erythema, blisters, and hyperpigmentation and scarring during the first 48 hours, a week, and two weeks after cryotherapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170818035762N3**

Registration date: **2020-05-30, 1399/03/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-30, 1399/03/10**

Update count: **0**

Registration date

2020-05-30, 1399/03/10

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4221 8021

Email address

a.kazeminejad@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of topical betamethasone valerate on post-cryotherapy inflammation in cutaneous wart treatment

Public title

betamethasone valerate on post-cryotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with skin wart who are diagnosed by a dermatologist clinically or pathologically and have cryotherapy indications. Patients over 2 years of age They have a conscious consent to enter the study the maximum number of warts is up to 20

Exclusion criteria:

pregnant and lactating women People treated with systemic medications that interfere with wound healing or immuno suppressive drugs Patients who have contraindications for cryotherapy Patients who have used topical medications other than emollients in the past month People who are allergic to betamethasone or topical steroids Patients with wound healing disorders such as diabetes Distributed and resistant warts that need further treatment

Age

From **2 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

we use medicine on one limb and use placebo. on another limb. executor of plan and Patient don't know which limb take the medicine.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mazandaran University of Medical Sciences

Street address

Central Headquarters of Mazandaran University of Medical Sciences,at the beginning of Valiasr Highway,Joibar Three Ways,Imam Square, Sari

City

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2019-02-16, 1397/11/27

Ethics committee reference number

IR.MAZUMS.REC.1398.298

Health conditions studied

1

Description of health condition studied

skin wart

ICD-10 code

B07

ICD-10 code description

Viral warts

Primary outcomes

1

Description

tolerance of pain to cryotherapy treatment

Timepoint

Day 1,7 and 14

Method of measurement

Vas scale

Secondary outcomes

1

Description

Illness severity

Timepoint

At the beginning of the study

Method of measurement

Based on the number of warts

2

Description

Duration of illness

Timepoint

At the beginning of the study
Method of measurement
Number of days before starting treatment

3

Description
Eritrea
Timepoint
The second, eighth and fifteenth day after starting treatment
Method of measurement
Based on the examination

4

Description
Blisters
Timepoint
The second, eighth and fifteenth day after starting treatment
Method of measurement
Based on the examination

5

Description
Scar
Timepoint
The second, eighth and fifteenth day after starting treatment
Method of measurement
Based on the examination

Intervention groups

1

Description
Intervention group: In our study, patients with skin warts in two different organs were included. The first intervention group was given one of the organs with betamethasone valrate after cryotherapy.

Category
Treatment - Drugs

2

Description
Control group: Control group: In our study, patients enter the study who have skin warts in two different organs. In the second intervention group, we used placebo on an organ that did not use betamethasone valrate

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center

Bo Ali Sina Hospital in Sari
Full name of responsible person
Armaghan Kazeminezhad
Street address
Sari. The beginning of Ghaem Shahr road. Bu Ali Sina Hospital
City
sari
Province
Mazandaran
Postal code
۳۳۹۷۱۴۸۱۵۷
Phone
+98 11 3304 4001
Email
publicrel@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Majid Saeedi
Street address
Downstairs pharmacy 13 Aban. Moalm Square. Sari.
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Phone
+98 11 3325 7230
Email
pajhooheshi@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person

Armaghan Kazeminezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street addressMazandaran University of Medical Sciences ,Sari ,
Mazandaran**City**

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 4221 8021

Fax

+98 11 4221 8022

Email

a.kazeminejad@mazums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.ArMarghan Kazeminejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street addressHeadquarters of Mazandaran University of Medical
Sciences. At the beginning of Valiasr Highway.Sari**City**

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3304 4001

Email

A.kazeminejad@mazums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.ArMarghan Kazeminejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street addressHeadquarters of Mazandaran University of Medical
Sciences. At the beginning of Valiasr Highway.Sari**City**

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3304 4001

Email

A.kazeminejad@mazums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent FormUndecided - 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**Title and more details about the data/document**Only part of the data, such as information about the
main outcome or the like, can be shared**When the data will become available and for how long**Start the access period 6 months after printing the
results**To whom data/document is available**Researchers working in academic and scientific
institutions**Under which criteria data/document could be used**Researchers working in academic and scientific
institutions**From where data/document is obtainable**

Email to: A.kazeminejad@mazums.ac.ir

What processes are involved for a request to access data/documentAfter communicating with the email if available, data and
results will be available**Comments**