

# 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 participating 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

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+98 11 3325 7230

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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

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sari

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**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 address**Headquarters of Mazandaran University of Medical  
Sciences. At the beginning of Valiasr Highway.Sari**City**

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**Province**

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**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 address**Headquarters of Mazandaran University of Medical  
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**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 3304 4001

**Email**

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**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 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**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/document**After communicating with the email if available, data and  
results will be available**Comments**