

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Comparison of intralesional 5-fluorouracil and cryotherapy in the treatment of common and palmoplantar warts

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Determination and comparison of the efficacy of intralesional 5-fluorouracil and cryotherapy in the treatment of common and palmoplantar warts

Last update: **2021-05-18, 1400/02/28**

Update count: **0**

#### Registration date

2021-05-18, 1400/02/28

#### Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 50 patients, single blinded, computerized randomized with permuted blocks

#### Registrant information

##### Name

Mozhdeh Sepaskhah

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 712125239

##### Email address

sepaskhah@sums.ac.ir

#### Settings and conduct

The study is conducted in the dermatology clinic of Shiraz University of Medical Sciences. Group 1 is treated by weekly intralesional 5-fluorouracil injection and group 2 by weekly cryotherapy. The patients are assessed at the beginning of treatment, and weeks 1, 2, 3, 4, 5, 6, 8, and 14 by lesion size calculation by ruler and dermatoscopy. The outcome assessor is blind to the type of treatment.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients of 16 years of age and higher; Common type warts; Palmoplantar type warts Exclusion criteria: Patients with more than 5 lesions; Pregnancy; Lactation; Patients with vascular, cardiovascular, hepatic, and chronic kidney disease; Patients with hypersensitivity to 5-fluorouracil, lidocaine, epinephrine, or cryotherapy; Beta-blocker drug consumption; Immunocompromised patients

#### Expected recruitment start date

2021-05-28, 1400/03/07

#### Expected recruitment end date

2022-03-20, 1400/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

Group 1: Intralesional 5-fluorouracil injection Group 2: Cryotherapy

#### Scientific title

Comparison of intralesional 5-fluorouracil and cryotherapy in the treatment of common and palmoplantar warts

#### Main outcome variables

Complete clinical cure

#### Public title

Comparison of efficacy of intralesional 5-fluorouracil and

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140212016557N6**

Registration date: **2021-05-18, 1400/02/28**

cryotherapy in the treatment of common and palmoplantar warts

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Patients of 16 years of age and higher Common type warts Palmoplantar type warts

#### **Exclusion criteria:**

Patients with more than 5 lesions Pregnancy Lactation Patients with vascular, cardiovascular, hepatic, and chronic kidney disease Patients with hypersensitivity to 5-fluorouracil, lidocaine, epinephrine, or cryotherapy Beta-blocker drug consumption Immunocompromised patients

### **Age**

From **16 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

- Outcome assessor

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software.

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

Due to the different treatment methods, the participants cannot be blinded. Principle investigator, and care provider physician are also aware of the type of drugs. But, outcome assessors are not aware of the treatment of each patient.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

Shiraz University of Medical Sciences, Zand St., Shiraz. Iran

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7134845794

##### **Approval date**

2021-02-14, 1399/11/26

##### **Ethics committee reference number**

IR.SUMS.MED.REC.1399.594

## **Health conditions studied**

### 1

#### **Description of health condition studied**

palmoplantar wart

#### **ICD-10 code**

B07.0

#### **ICD-10 code description**

Plantar wart

### 2

#### **Description of health condition studied**

Common wart

#### **ICD-10 code**

B07.8

#### **ICD-10 code description**

Other viral warts

## **Primary outcomes**

### 1

#### **Description**

Complete clinical cure

#### **Timepoint**

At the beginning of treatment, and weeks 1, 2, 3, 4, 5, 6, 8, and 14

#### **Method of measurement**

Lesion size calculation by ruler and dermatoscopy

## **Secondary outcomes**

### 1

#### **Description**

Pain during treatment

#### **Timepoint**

Weeks 1, 2, 3, 4, 5, 6

#### **Method of measurement**

Pain illustrated numerical rating scale

### 2

#### **Description**

Quality of life

#### **Timepoint**

At the beginning of treatment, and the end of treatment

#### **Method of measurement**

Dermatology quality of life index Persian version

## Intervention groups

### 1

#### Description

Intervention group: Intralesional 5-fluorouracil injection, once weekly, for 6 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Cryotherapy, once weekly, for 6 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic, Shahid Faghihi hospital

##### Full name of responsible person

Mozhdeh Sepaskhah

##### Street address

Dermatology clinic, Faghihi hospital, Zand St.

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3212 5239

##### Email

sepaskhah@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Abbas Rezaian zade

##### Street address

Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

1433671348

##### Phone

+98 71 3212 2430

##### Email

vcrdep@sums.ac.ir

##### Grant name

Research grant of the Research Council of Shiraz University of Medical Sciences

##### Grant code / Reference number

20139

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

Yes

##### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Mina Bazyar

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Dermatology clinic, Faghihi hospital, Zand St., Shiraz, Iran

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##### Postal code

7134844119

##### Phone

+98 71 3231 9049

##### Fax

+98 71 3231 9049

##### Email

minabazyar@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mozhdeh Sepaskhah

##### Position

Associate professor

##### Latest degree

Subspecialist

**Other areas of specialty/work**

Dermatology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mozhdeh Sepaskhah

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dermatology

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**Email**

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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