Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim
Determination and comparison of the effuicacy of intralesional 5-fluorouracil and cryotherapy in the treatment of common and palmoplantar warts

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

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.

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-flurouracil, lidocaine, epinephrine, or cryotherapy; Beta-blocker drug consumption; Immunocompromised patients

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

Main outcome variables
Complete clinical cure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140212016557N6**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**
Update count: **0**

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

Registrant information

Name
Mozhdeh Sepaskhah

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 712125239

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sepaskhah@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

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

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

Public title
Comparison of efficacy of intralesional 5-fluorouracil and

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-flurouracil, 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 pf 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.
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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
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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
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Person responsible for scientific inquiries

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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

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Latest degree

Subspecialist

Other areas of specialty/work

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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