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

Protocol summary

Study aim
Determination and comparison of the efficacy 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-fluorouracil, 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
Email address
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 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 3231 9049
Fax
+98 71 3231 9049
Email
minabazyar@yahoo.com
Web page address

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
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3212 5239
Email
sepaskhah@sums.ac.ir

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

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

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 712125239

Fax
+98 71 3231 9049

Email
sepaskhah@sums.ac.ir

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