Clinical Trial Protocol
Iranian Registry of Clinical Trials
25 Jul 2022

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)

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+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 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.
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7134844119
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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
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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
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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
**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
- **Street address**: Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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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