

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Comparison of the effect of intralesional injection of triamcinolone acetonide with the simultaneous combination of triamcinolone acetonide and 5-fluoracil in the treatment of hypertrophic scars

#### Protocol summary

##### Study aim

Comparison of the effect of intralesional injection of triamcinolone acetonide with the simultaneous combination of triamcinolone acetonide and 5-fluoracil in the treatment of hypertrophic scars

##### Design

This is a randomized, and non-blinded clinical trial with a parallel design. In this randomized study, 40 eligible patients will be included in the study. A table of random numbers is used for randomization, and the participants are assigned to two intervention groups.

##### Settings and conduct

This study, which will be conducted in the Haj Dayi Clinic of Kermanshah, is nonblinded. The two studied groups will be matched in terms of age, gender, and duration of the lesion.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent Exclusion criteria: Patients under treatment for the last 6 months; Pregnant patients or those planning to become pregnant; Lactating women; Chronic kidney disease patients or those with any abnormal changes in CBC or liver function tests

##### Intervention groups

In the first intervention group, 20 mg of triamcinolone acetonide (manufactured by Alborz Company) will be used inside the lesion once every four weeks for 6 treatment sessions (that is, injection of 50% of triamcinolone acetonide (40 mg). In the second intervention group, 50% triamcinolone acetonide injection (40 mg) and 50% 5-Fluoracil (manufactured by Alborz company) (50 mg) will be used. Finally, the combination of 20 mg of triamcinolone acetonide with 25 mg of 5-Fluoracil is prepared for injection and is injected to patients every 4 weeks.

##### Main outcome variables

the intensity of itching of the lesion; the intensity of

redness of the lesion; Length, width, and height of the lesion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N189**

Registration date: **2022-10-25, 1401/08/03**

Registration timing: **prospective**

Last update: **2022-10-25, 1401/08/03**

Update count: **0**

##### Registration date

2022-10-25, 1401/08/03

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

froughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-16, 1401/08/25

##### Expected recruitment end date

2023-01-05, 1401/10/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of intralesional injection of triamcinolone acetonide with the simultaneous combination of triamcinolone acetonide and 5-fluoracil in the treatment of hypertrophic scars

**Public title**

Comparison of the effect of intralesional injection of triamcinolone acetonide with the simultaneous combination of triamcinolone acetonide and 5-fluoracil

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Informed consent

**Exclusion criteria:**

Patients under treatment for the last 6 months Pregnant patients or those planning to become pregnant Lactating women Chronic kidney disease patients or those with any abnormal changes in CBC or liver function tests

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the random number table, patients are divided into two groups of 20. Each patient is assigned a 4-digit code based on the random number table; based on the right number of patients' codes, the patients are divided into two groups. Patients whose last digit is 2, 4, 6, and 8 will be assigned to the intervention group, and patients whose last digit is 1,3,5, and 7 will be assigned to the control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2022-06-26, 1401/04/05

**Ethics committee reference number**

IR.KUMS.MED.REC.1401.068

**Health conditions studied****1****Description of health condition studied**

Hypertrophic scar

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Intensity of itching of the lesion

**Timepoint**

First, fourth and sixth week

**Method of measurement**

Based on examination and questioning of the patient

**2****Description**

Redness intensity of the lesion

**Timepoint**

First, fourth and sixth week

**Method of measurement**

Based on examination

**3****Description**

Length, width and height of the lesion

**Timepoint**

First, fourth and sixth week

**Method of measurement**

Based on examination

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

In the first intervention group, 20 mg of triamcinolone acetonide (manufactured by Alborz Company) will be used inside the lesion once every four weeks for 6 treatment sessions (that is, injection of 50% of triamcinolone acetonide (40 mg).

#### Category

Treatment - Drugs

### 2

#### Description

In the second intervention group, 50% triamcinolone acetonide injection (40 mg) and 50% 5-Fluoracil (manufactured by Alborz company) (50 mg) will be used. Finally, the combination of 20 mg of triamcinolone acetonide in 25 mg of 5-Fluoracil is prepared for injection and is injected to patients every 4 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Haji Dayi skin clinic

##### Full name of responsible person

Abdolhamid Ebrahimi

##### Street address

Golestan Crossroads

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714647147

##### Phone

+98 83 3845 3486

##### Email

pamiebi1377@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Cyrus Jalili

##### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

cjalili@kums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Abdolhamid Ebrahimi

##### Position

Resident of Skin

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Skin

##### Street address

School of Medicine, parastar boulevard

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3427 4618

##### Email

pamiebi1377@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Hossein Kavosi

##### Position

Member of the academic staff of Kermanshah  
University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Skin

**Street address**

School of Medicine, parastar boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

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+98 83 3427 4618

**Email**

hkawosi@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Abdolhamid Ebrahimi

**Position**

Resident of Skin

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Skin

**Street address**

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6715847141

**Phone**

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**Email**

pamiebi1377@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available