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)
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+98 83 1821 4653
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fforoughi@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 boulvarde
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Postal code
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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

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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

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City
Kermanshah

Province
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6715847141

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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