Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of intralesional injection of hyalase, steroid and 5-fluorouracil with intralesional steroid and 5-fluorouracil in patients with keloids

Protocol summary

Study aim
Evaluation of the effect of using hyalase in treatment of patients with keloid lesions

Design
A randomized, double blinded, controlled clinical trial with a parallel group design of 16 patients. Block randomization has been done.

Settings and conduct
The study will be performed on 16 patients in Razi Hospital in Tehran. The number of treatment sessions in both groups is 3 sessions for 3 months at intervals of 3 to 4 weeks. Before starting treatment, patients' keloid lesions are photographed. This will be repeated at the end of treatment and 2 months after the end of treatment. Finally, in order to blind the study, the photos and information of the lesions taken at these three different times are examined by two other physicians (except the treating physician).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with keloid lesions who have not received any other treatments for at least 6 months before or at the same time as starting the treatment.
Exclusion criteria: Patients with coagulation disorders or hematologic disorders; patients taking blood-thinning drugs such as aspirin.

Intervention groups
The number of participants in this intervention is 16 people, which includes a control group and an intervention group. The control group receive intralesional 0.2 cc of 5-fluorouracil from a vial of 250mg/5ml 5-fluorouracil and a 10 mg triamcinolone injection. Patients in the intervention group, in addition to receiving the two drugs mentioned at the same dose as the control group, will also receive intralesional hyalase at a dose of 30 UI/ml. The number of treatment sessions in both groups is 3 sessions for 3 months at intervals of 3 to 4 weeks.

Main outcome variables
Height and diameter of the lesion; color; consistency; pain and itching; skin atrophy; telangiectasia; hypopigmentation and hyperpigmentation; ulcer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220115053715N1**
Registration date: **2022-01-28, 1400/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-28, 1400/11/08**
Update count: **0**

Registration date
2022-01-28, 1400/11/08

Registrant information

Name
Fatemeh Sima

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8474 2616

Email address
f-sima@student.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of intralesional injection of hyalase, steroid and 5-fluorouracil with intralesional steroid and 5-fluorouracil in patients with keloids

Public title

Evaluation of the effect of hyalase in treatment of keloids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with keloid lesions based on clinical diagnosis or pathology who have not received any other treatments for at least 6 months prior to or at the same time as initiating treatment.

Exclusion criteria:

Patients with coagulation disorders or hematologic disorders such as hemophilia. Patients taking blood-thinning drugs such as aspirin.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

By assigning a number to each patient and using the blocked randomization site, patients are randomly assigned to one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients will not be informed which of the two treatment groups they are in. Also, two physicians who are not aware of the treatment received by each patient will evaluate the outcomes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of school of medicine-Tehran University of Medical Sciences

Street address

Education Bldg, Tehran University of Medicine, Poursina St.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1166

Health conditions studied

1

Description of health condition studied

keloid

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

keloid lesion diameter

Timepoint

Before treatment, end of treatment and 2 months after the end of treatment

Method of measurement

Using a ruler and Vancouver scar scale

2

Description

Height of keloid lesion

Timepoint

Before treatment, end of treatment and 2 months after the end of treatment

Method of measurement

Using a ruler and Vancouver scar scale

3

Description

keloid lesion color

Timepoint

Before treatment, end of treatment and 2 months after the end of treatment

Method of measurement
Observe in natural light and Vancouver scar scale

4

Description
pain
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Asking patient about pain in the lesion

5

Description
consistency
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Observing and touching the lesion and Vancouver scar scale

6

Description
itching
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Asking patient about presence of itching in the lesion

7

Description
Skin atrophy
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Observing the lesion

8

Description
Telangiectasia
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Observing the lesion in terms of the appearance of arteries as fine red lines on the skin

9

Description
Hypopigmentation and hyperpigmentation
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Observing the lesion in terms of decrease or increase of skin pigments and Vancouver scar scale

10

Description
Ulcer
Timepoint
Before treatment, end of treatment and 2 months after the end of treatment
Method of measurement
Observing the lesion in terms of presence of ulcers

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in the control group will receive intralesional injections of 5-fluorouracil 0.2 cc from vials of 5-fluorouracil 250mg/5ml and triamcinolone 10 mg in 3 sessions for 3 months at intervals of 3 to 4 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in the intervention group will receive intralesional injections of 5-fluorouracil 0.2 cc from vials of 5-fluorouracil 250mg/5ml and triamcinolone 10 mg and hyalase 30 IU/ml in 3 sessions for 3 months at intervals of 3 to 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi dermatology hospital
Full name of responsible person
Dr. Amir Hooshang Ehsani
Street address
Razi skin hospital, Razi Ave, Vahdate eslami Ave, Hafiz St.
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 5561 8989
Email
Ehsanih@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Qods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Sima
Position
medical student
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
Street address
Razi skin hospital, Razi Ave, Vahdate eslami Ave, Hafiz St, Tehran city
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 5561 8989
Email
f-Sima@student.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Amir Hooshang Ehsani
Position
full professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Razi skin hospital, Razi Ave, Vahdate eslami Ave, Hafiz St.
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 5561 8989
Email
Ehsanih@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Sima
Position
medical student
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
Street address
Razi skin hospital, Razi Ave, Vahdate eslami Ave, Hafiz St.
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 5561 8989
Email
f-Sima@student.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
IPD collected for the primary outcome measure only
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Scientific research
From where data/document is obtainable
Dr. Amir Hooshang Ehsani; Fatemeh Sima
What processes are involved for a request to access data/document
The application is sent by official university email which should contain the recipient's information and the purpose of his/her request. After having verified the accuracy of the information, files would be sent.
Comments