

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparing the effectiveness of intralesional injection of steroid in keloid treatment with and without cryotherapy: a randomized controlled trial

#### Protocol summary

##### Study aim

Investigating the effect of triamcinolone acetonide injection in keloid alone and with cryotherapy

##### Design

A randomized clinical trial that is performed simultaneously in two parallel intervention groups including 32 patients and a total of 64 keloid lesions.

##### Settings and conduct

This study will be carried out at Razi hospital for 32 patients and 64 keloid lesions. In each patient two keloid lesions will be detected and treated, one lesion is treated with steroid and the other lesion is treated with cryotherapy plus steroid.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-65 years, no previous intralesional injection of verapamil or triamcinolone, existence of more than two keloid lesions. Exclusion criteria: pregnancy, lactation, kidney or liver disease, hematologic disease or bone marrow suppression, systemic or local infection, keloid lesion on face

##### Intervention groups

This study includes two groups. Intervention of each group will be performed on one side of the body which is randomly chosen. The first group of intervention will undergo intralesional injection of triamcinolone acetonide alone and the second group will get intralesional injection of triamcinolone acetonide along with cryotherapy

##### Main outcome variables

The main outcome of the study is to compare the effectiveness of two treatment methods on keloid lesions which is evaluated by POSAS (patient and observer scar assessment scale) questionnaire.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230124057201N2**

Registration date: **2023-03-24, 1402/01/04**

Registration timing: **prospective**

Last update: **2023-03-24, 1402/01/04**

Update count: **0**

##### Registration date

2023-03-24, 1402/01/04

##### Registrant information

###### Name

Zeinab aryanian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5563 0853

###### Email address

z\_aryanian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-03, 1402/01/14

##### Expected recruitment end date

2023-09-05, 1402/06/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effectiveness of intralesional injection of steroid in keloid treatment with and without cryotherapy: a randomized controlled trial

##### Public title

Effectiveness of steroid injection with and without cryotherapy in the treatment of keloid scars

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age between 18-65 years Patients who didn't have prior intralesional injection with steroid or verapamil More than two lesions are available

##### **Exclusion criteria:**

Pregnant patients or patients who are intended to get pregnant Lactation Underlying kidney or liver disease Hematologic disorder or bone marrow suppression Presence of systemic or local infection Keloid in the face area

#### **Age**

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

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **2**

One side will have single injection of steroid and the other side will have steroid injection with cryotherapy

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Random allocation was done with triamcinolone Tr.A and combined treatment Tr.B. Each person is considered as a block. Double blocks are made in a way that the combination AB (A:Tr.A and B:Tr.B) means the right side of person is injected with Tr.A, and the left side is injected with Tr.B. A random number table was used for the random list. a random number was selected, if the number was between 0 and 4, AB combination and if it was between 5 and 9, BA combination was used, this process is repeated until all Eligible patients are included in the study.

#### **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 tehran university of medical science

##### **Street address**

Tehran University of medical science, ghods street, keshavarz boulevard

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417613151

##### **Approval date**

2023-01-29, 1401/11/09

##### **Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1401.723

#### **2**

##### **Ethics committee**

##### **Name of ethics committee**

ethics committee of tehran university of medical science

##### **Street address**

Tehran University of medical science, ghods street, keshavarz boulevard

##### **City**

Tehtan

##### **Province**

Tehran

##### **Postal code**

1417613151

##### **Approval date**

2023-01-29, 1401/11/09

##### **Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1401.723

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Keloid

##### **ICD-10 code**

L73.0

##### **ICD-10 code description**

Acne keloid

### **Primary outcomes**

#### **1**

##### **Description**

Effectiveness of steroid will be assessed based on POSAS questionnaire

##### **Timepoint**

Month 0(baseline), month 3 and month 6

##### **Method of measurement**

POSAS(patient and observer scar assessment scale)

### **Secondary outcomes**

## 1

### Description

Effectiveness of steroid with and without cryotherapy based on Fitzpatrick skin type

### Timepoint

Month 0(baseline), month 3 and month 6

### Method of measurement

Fitzpatrick skin type classification

## Intervention groups

## 1

### Description

Intervention group: Keloid lesions of this group will receive intralesional injection of triamcinolone acetonide (40mg/ml) with maximum dose of 20mg/ml for each lesion. injection will be performed every 3 weeks for a total of 4 sessions.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: This group of intervention will first receive cryotherapy based on the physician's experience and past guidelines, then immediately the lesion will be injected with triamcinolone acetonide (40 mg/ml) with maximum dose of 20mg/ml, every 3 weeks for a total of 4 sessions.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Razi hospital

#### Full name of responsible person

Dr.Zeinab Aryanian

#### Street address

Razi hospital, Vahdat Eslami Square,Vahdat Eslami Avenue,Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1199663911

#### Phone

+98 21 5563 0553

#### Email

razihospital@sina.tums.ac.ir

#### Web page address

<https://razihos.tums.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Akbar Fotouhi

#### Street address

Research and technology affairs, central building of tehran university of medical science, ghods street, keshavarz boulevard

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Phone

+98 21 8163 3102

#### Email

itcenter@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

Dr. Zeinab Aryanian

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dermatology

#### Street address

Razi hospital, Vahdat Eslami Square, Vahdat Eslami Avenue, Tehran

#### City

Tehran

#### Province

Tehran

**Postal code**  
1199663911  
**Phone**  
+98 21 5563 0553  
**Email**  
z\_aryanian@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Zeinab Aryanian  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Razi hospital, Vahdat Eslami Square, Vahdat Eslami Avenue, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1199663911  
**Phone**  
+98 21 5563 0553  
**Email**  
z\_aryanian@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Sama Heidari

**Position**  
General physician  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Razi hospital, Vahdat Eslami Square, Vahdat Eslami Avenue, Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1199663911  
**Phone**  
+98 21 5563 0553  
**Email**  
sama.h9473@gmail.com

## 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