

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparison of intralesional vitamin D with intralesional triamcinolone acetone in the treatment of keloids

#### Protocol summary

##### Study aim

Comparison of intralesional vitamin D with intralesional triamcinolone acetone in the treatment of keloids

##### Design

A clinical trial with a control group, with parallel groups, without blinding, simple randomization, phase 3 on 26 patients, rand function of Excel software is used for randomization.

##### Settings and conduct

Patients referred to the dermatology clinic of Imam Khomeini Hospital in Ahvaz

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness and cooperation to participate in the study; both genders and with the age of 18 to 60 years; all patients have two or more keloids; the duration of lesions is less than 5 years and they have not been treated so far; keloids with sizes different maximum 5 cm and in different parts of the body.

Exclusion criteria: unwillingness to participate in the study; keloids in the face area; active infection in or near the keloid site; pregnant or lactating patients; People with underlying diseases such as diabetes; mental illness; cancer and heart disease

##### Intervention groups

Case group: Intralesional injection of vitamin D ampoule 300,000 units with a dose of 0.2 ml per 1 cm of the lesion. Maximum one milliliter of vitamin D is injected in each lesion. Treatment sessions are once every 3 weeks and the treatment lasts up to The flattening of the scar continues; an average of 6 sessions is considered as the duration of the patient's treatment). In the control group, triamcinolone is injected into the lesion with a concentration of 40 mg per milliliter in a maximum of six sessions, a maximum of one per lesion. ml is injected, the injection intervals in this treatment are done every 3 weeks.

##### Main outcome variables

Keloid size, grading based on Vancouver scar scale(vss) and complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220902055857N1**

Registration date: **2022-09-07, 1401/06/16**

Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

##### Registration date

2022-09-07, 1401/06/16

##### Registrant information

##### Name

Sedigheh Sananzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3311 0000

##### Email address

sananzadeh.s@ajums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-09-23, 1401/07/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Comparison of intralesional vitamin D with intralesional triamcinolone acetonide in the treatment of keloids |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Public title</b>                                                                                          | Effect of intralesional vitamin D in treatment of keloid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Purpose</b>                                                                                               | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Inclusion/Exclusion criteria</b>                                                                          | <p><b>Inclusion criteria:</b><br/>Willingness and cooperation to participate in the study<br/>All patients with two or more keloids<br/>The duration of lesions should be less than 5 years and they have not been treated yet<br/>keloids with different sizes up to 5 cm and in different parts of the body</p> <p><b>Exclusion criteria:</b><br/>keloid on face<br/>active infection in or near the keloid site<br/>pregnant or lactating patients<br/>patients with underlying diseases such as diabetes, mental illness, cancer and heart disease</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Age</b>                                                                                                   | From <b>18 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Gender</b>                                                                                                | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Phase</b>                                                                                                 | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Groups that have been masked</b>                                                                          | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Sample size</b>                                                                                           | <p>Target sample size: <b>26</b><br/>More than 1 sample in each individual<br/>Number of samples in each individual: <b>2</b><br/>Every patient has two keloids</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Randomization (investigator's opinion)</b>                                                                | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Randomization description</b>                                                                             | The simple random assignment method is that for patients with one lesion, odd numbers are given to the intervention group (new treatment) and even numbers are given to the control group (common treatment). Then, according to the number of the studied sample, the relevant numbers are extracted using the computer, each number is written on a card and placed in an envelope, and the envelopes are sealed, and the patient's number is written on each envelope, and the first patient in The study is registered and entered into the study, the envelope related to patient number 1 and envelope number 2 will be given to the second patient. In the same way, this work will continue until the end of the sample size of the study. In order to maintain randomization, the person who prepares the envelopes with The person who registers the patients and provides the envelopes to the patients should be different. For patients who have two lesions, one envelope is given for the right side lesions and the highest lesion. |
| <b>Blinding (investigator's opinion)</b>                                                                     | Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Blinding description</b>                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Placebo</b>                                                                                               | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Assignment</b>                                                                                            | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Other design features</b>                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of JundiShapur Ahvaz University of Medical Sciences

##### Street address

Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences; Golestan Blvd

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6193673166

#### Approval date

2022-06-21, 1401/03/31

#### Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.063

## 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 score in the Vancouver Scar scale

#### Timepoint

Vancouver scar scale upon arrival, 3, 6, 9, 12, 15 weeks after each injection session until the lesion is completely flattened or up to 6 sessions

#### Method of measurement

Vancouver scar scale

## Secondary outcomes

### 1

#### Description

Patient satisfaction from treatment

#### Timepoint

End of treatment

#### Method of measurement

Visual Analogue Scale

## Intervention groups

### 1

#### Description

Intervention group: Intralesional injection of vitamin D ampoule from Caspian Pharmaceutical Company will be prescribed to patients. Vitamin D ampoule 300,000 units will be injected at a dose of 0.2 ml per 1 cm of the lesion. A maximum of one milliliter of vitamin D will be injected into each lesion. The intervals of the treatment sessions are once every 3 weeks and the treatment continues until the scar flattens; an average of 6 sessions is considered the duration of the patient's treatment.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Intralesional injection of triamcinolone from EXIR with a concentration of 40 mg per milliliter is used in a maximum of six sessions, a maximum of one milliliter is injected in each lesion, the injection intervals in this treatment are also done once every 3 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital of Ahvaz

##### Full name of responsible person

Nader Pazayr

##### Street address

Imam khomeini Medicinal Academic Center,  
Azadegan Ave

##### City

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##### Province

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6193673111

##### Phone

+98 61 3222 2922

##### Email

sananzadeh.s@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehrnoosh Zakerkish

##### Street address

Ground floor, Vice chancellor of research, Ahvaz

Jundishapour University of Medical Sciences,  
Daneshgahi Town, Ahvaz

##### City

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##### Province

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##### Fax

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##### Email

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##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Sedigheh Sananzadeh

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

No. 8; Row 1013; Valiasr St

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

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Nader Pazyar

**Position**

Associate Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No. 8; Row 1013; Valiasr St

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**Phone**

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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