

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of intralesional Vitamin D versus intralesional Triamcinolone Acetonide on the treatment of keloids: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of intralesional Vitamin D versus intralesional Triamcinolone Acetonide on the treatment of keloids

Design

This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which 24 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Sina Hospital in Hamadan city, involving 24 eligible patients with keloids. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double -blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years, Keloid lesion with a maximum size of 5 cm, less than 5 years old, Exclusion Criteria: Pregnancy or breastfeeding, History of prior treatment within the last 3 to 4 months, Keloid lesion on the face, Active infection at the keloid lesion site.

Intervention groups

Intervention group: Intralesional injection of vitamin D 300,000 units (manufactured by Caspian Pharmaceutical Co.) at a concentration of 0.2 per mL, with a maximum dose of 1 mL per lesion, using a 1 cc syringe and a 24-gauge needle, once every 3 weeks, for a maximum of 6 sessions Control Group: Intralesional injection of triamcinolone acetonide (manufactured by Exir Pharmaceutical Co.) at a concentration of 40 mg per mL, with a maximum dose of 1 mL per lesion, using a 1 cc syringe and a 24-gauge needle, once every 3 weeks, for a maximum of 6 sessions.

Main outcome variables

Primary outcome: Scar severity; Pain intensity Secondary outcome: Local complications (burning sensation, pain,

itching, inflammation)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N609**

Registration date: **2026-05-14, 1405/02/24**

Registration timing: **prospective**

Last update: **2026-05-14, 1405/02/24**

Update count: **0**

Registration date

2026-05-14, 1405/02/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-31, 1405/03/10

Expected recruitment end date

2026-11-01, 1405/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intralesional Vitamin D versus intralesional Triamcinolone Acetonide on the treatment of keloids: a double-blind randomized clinical trial

Public title

Effect of intralesional Vitamin D versus intralesional Triamcinolone Acetonide on the treatment of keloids

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 60 years, Keloid lesion with a maximum size of 5 cm, less than 5 years old,

Exclusion criteria:

Pregnancy or breastfeeding, History of prior treatment within the last 3 to 4 months, Keloid lesion on the face, Active infection at the keloid lesion site.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the medications will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

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Hamadan

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6517838695

Approval date

2026-04-25, 1405/02/05

Ethics committee reference number

IR.UMSHA.REC.1405.066

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**

Scar severity

Timepoint

Before the intervention and three months later

Method of measurement

Using the Vancouver Scar Scale (VSS)

2**Description**

Pain intensity

Timepoint

Before the intervention and three months later

Method of measurement

Using the Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Local complications (burning sensation, pain, itching, inflammation)

Timepoint

Three months after the intervention

Method of measurement

By taking a medical history and performing a clinical examination

Intervention groups

1

Description

Intervention group: Intralesional injection of vitamin D 300,000 units (manufactured by Caspian Pharmaceutical Co.) at a concentration of 0.2 per mL, with a maximum dose of 1 mL per lesion, using a 1 cc syringe and a 24-gauge needle, once every 3 weeks, for a maximum of 6 sessions

Category

Treatment - Drugs

2

Description

Control Group: Intralesional injection of triamcinolone acetone (manufactured by Exir Pharmaceutical Co.) at a concentration of 40 mg per mL, with a maximum dose of 1 mL per lesion, using a 1 cc syringe and a 24-gauge needle, once every 3 weeks, for a maximum of 6 sessions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr Seyyed Mohammad Noorolahi

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Seyyed Mohammad Noorolahi

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person

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Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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