Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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
Province
Hamadan
Postal code
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 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.
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
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Sponsors / Funding sources

1

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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
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Other areas of specialty/work
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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