Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

Study aim
Comparison of intralesional vitamin D with intralesional triamcinolone acetonide 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

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Iran (Islamic Republic of)

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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

Public title
Effect of intralesional vitamin D in treatment of keloid
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness and cooperation to participate in the study All patients with two or more keloids The duration of lesions should be less than 5 years and they have not been treated yet keloids with different sizes up to 5 cm and in different parts of the body
Exclusion criteria:
keloid on face active infection in or near the keloid site pregnant or lactating patients patients with underlying diseases such as diabetes, mental illness, cancer and heart disease
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **26**
More than 1 sample in each individual
Number of samples in each individual: **2**
Every patient has two keloids
Randomization (investigator's opinion)
Randomized
Randomization description
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.
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 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 Pazyar
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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