Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 groups will be performed on one side of the body which is randomly chosen. 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
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Iran (Islamic Republic of)
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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 sience, 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 tehtan university of medical science

Street address

Tehran University of medical sience, 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran 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
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
Assisstant professor
Latest degree
Specialist
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Postal code
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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