Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of intralesional Bleomycin plus cryotherapy versus intralesional Triamcinolone plus cryotherapy in the treatment of keloid

Protocol summary

Study aim
More effective treatment for keloid lesions
Design
A randomized, clinical trial with a parallel group design
Settings and conduct
Patients with keloid who referred to the dermatology clinic of Shohada and Loghman Hospitals in 1398۹ were divided into two groups of intervention and control based on a random table
Participants/Inclusion and exclusion criteria
Inclusion criteria include skin type 2 to 5 based on Fitzpatrick,having 1 to 3 keloids 1 to 5 cm in diameter from neck to bottom.also,Exclusion criteria include hypersensitivity to bleomycin, pregnancy, and lactation
Intervention groups
The intervention group will receive intralesional Bleomycin with cryotherapy and the control group will receive intralesional Triamcinolone with cryotherapy
Main outcome variables
Pigmentation; vascularity; flexibility; thickness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200108046060N1**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-18, 1398/10/28**
Update count: **0**
Registration date
2020-01-18, 1398/10/28

Registrant information
Name
Ali Forghanian
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-01-10, 1398/10/20
Expected recruitment end date
2020-05-09, 1399/02/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of intralesional Bleomycin plus cryotherapy versus intralesional Triamcinolone plus cryotherapy in the treatment of keloid

Public title
Effect of Bleomycin plus cryotherapy in treatment of keloid
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Skin type 2 to 5 based on Fitzpatrick Having 1 to 3 keloids 1 to 5 cm in diameter from neck to bottom
Exclusion criteria:
Unwillingness to participate in the study Hypersensitivity

to Bleomycin Pregnancy Lactation

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups by simple randomization method based on random number table.

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 Shahid Beheshti University of Medical Science

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2019-12-24, 1398/10/03

Ethics committee reference number
IR.SBMU.SRC.REC.1398.021

Health conditions studied

1

Description of health condition studied
Keloid

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Vancouver Scar Scale

Timepoint
At baseline and 3 months after onset

Method of measurement
Vancouver Scar Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intralesional Bleomycin plus cryotherapy

Category
Treatment - Drugs

2

Description
Control group: Intralesional Triamcinolone plus cryotherapy

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish hospital

Full name of responsible person
Forghanian Ali

Street address
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2

Recruitment center

Name of recruitment center
Loghman hospital

Full name of responsible person
Forghanian Ali

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Sponsors / Funding sources

1

Sponsor
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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
Shahid Beheshti 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
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Resident
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All study data will be shared, after unidentifiable individuals

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For further research

From where data/document is obtainable

Forghanian Ali

What processes are involved for a request to access data/document

Send request by email to the responsible person

Comments