

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 1398, 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1507

Email address

ali_forghanian8611@sbmu.ac.ir

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
Tajrish Sq, Tajrish hospital

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2274 9201

Email
Ali_forghanian8611@sbmu.ac.ir

2

Recruitment center

Name of recruitment center
Loghman hospital

Full name of responsible person
Forghanian Ali

Street address
Loghman hospital, Makhsus St
City
Tehran
Province
Tehran
Postal code
1333631151
Phone
+98 21 5541 9005
Email
ali_forghanian8611@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zarghi Afshin
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak, Tehran
City
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Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9781
Email
Mpajouhesh@sbmu.ac.ir

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Forghanian Ali
Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Dermatology Department, Loghman Hospital,
Makhsus St

City

Tehran

Province

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Postal code

1333625445

Phone

+98 21 5541 9005

Email

ali_forghanian8611@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mozafari Nikoo

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

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1333625445

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Email

nikoo_md@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Forghanian Ali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Email
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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