

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

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1989934148

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2

Recruitment center

Name of recruitment center

Loghman hospital

Full name of responsible person

Forghanian Ali

Street address

Loghman hospital, Makhsus St

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Province

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zarghi Afshin

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

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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**

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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mozafari Nikoo

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

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Other areas of specialty/work

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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