

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of intralesional bleomycin plus intralesional triamcinolone in the treatment of keloids in the year of 1401 in Loghman and Tajrish hospital

Protocol summary

Study aim

Evaluation of the efficacy of keloid treatment by intralesional injection of bleomycin in combination with triamcinolone intralesional injection.

Design

Clinical trial before and after, without control group, with single groups, no blinding, no randomization, phase 2 on 30 patients.

Settings and conduct

In this study, patients with refractory keloid are treated according to the definition of referring outpatient to Loghman and Shohada-ye Tajrish dermatology clinic in Tehran. Drug injection will be repeated every four weeks and up to 6 sessions with a combination of bleomycin and triamcinolone acetonide, and lidocaine with a ratio of 3:3:3. The VSS (Vancouver Scar Scale) scale will be used to evaluate the efficacy of two treatments at the beginning of the study and the end of the treatment.

Participants/Inclusion and exclusion criteria

Patients between the ages of 18 and 60 with refractory keloid lesions referred to the dermatology clinic of Loghman and Shohada-e-Tajrish hospitals in 1401-1402 will be included in the study; Exclusion criteria: dissatisfaction with the study, sensitivity to bleomycin, pregnant or lactating women.

Intervention groups

treatment of refractory keloid by intralesional injection of bleomycin in combination with triamcinolone intralesional injection.

Main outcome variables

Pigmentation of keloid lesions; pliability of keloid lesions; vascularity of keloid lesions; thickness of keloid lesions; recurrence rate; the number of sessions needed for keloid treatment; complications of treatment including PIH, atrophy, wound, new scarring, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221209056760N1**

Registration date: **2023-02-17, 1401/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-17, 1401/11/28**

Update count: **0**

Registration date

2023-02-17, 1401/11/28

Registrant information

Name

Faeghe Mollaabasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7781 2053

Email address

faegheabasi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intralesional bleomycin plus intralesional triamcinolone in the treatment of keloids in the year of 1401 in Loghman and Tajrish hospital

Public title

Comparison of the efficacy of intralesional bleomycin plus intralesional triamcinolone in the treatment of keloids.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the ages of 18 and 60 Refractory keloid: Relapse or not cured despite six sessions of intra-triamcynolone acetonide injection.

Exclusion criteria:

Dissatisfaction with the study sensitivity to bleomycin pregnant or breast feeding

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Shahid Beheshti Univ., Shahid Shahriari Sq. Velenjak, Tehran, P.C. 1983969411. I.R.Iran.

City

Tehran

Province

Tehran

Postal code

198396-3113

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

IR.SBMU.SRC.REC.1401.010

Health conditions studied

1

Description of health condition studied

keloid

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of the efficacy of keloid treatment by intralesional injection of bleomycin in combination with intralesion injection of triamcinolone.(pigmentation, vascularity, pliability and thickness)

Timepoint

The Beginning of the study and then every 4 weeks and up to 6 sessions (end of study).

Method of measurement

The VSS (Vancouver Scar Scale) scale and examining the patient.

Secondary outcomes

1

Description

Relapse rate

Timepoint

Beginning of the study and then every 4 weeks and up to 6 sessions (end of study)

Method of measurement

The VSS (Vancouver Scar Scale) scale

2

Description

Complication of treatment.

Timepoint

Beginning of the study and then every 4 weeks and up to 6 sessions (end of study).

Method of measurement

observation and asking for the patients.

Intervention groups

1

Description

Intervention group: Patients with refractory keloids referred to the dermatology clinic of Loghman Hakim and Shohada Tajrish hospitals will be treated with intra-

lesional of bleomycin 5 mg and triamcinolone acetonide 40 mg and lidocaine 2% in combination 3:3:3 and every 4 weeks and up to 6 sessions.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Loghman hospital

Full name of responsible person

Faeghe Mollaabasi

Street address

Makhsous Ave

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2**Recruitment center****Name of recruitment center**

Shohada Tajrish hospital

Full name of responsible person

Faeghe Mollaabasi

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Tajrish Sq

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Robati

Street address

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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

Faeghe Mollaabasi

Position

Resident of dermatology

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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Position

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD**Study Protocol**

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available