Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the efficacy of intralesional bleomycin plus intralesional triamcinolone in the treatment of keloids in the year of 1401in 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 1401in 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-triamcyonolone 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 bleomycincin 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

City
Tehran

Province
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1461965381

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2

Recruitment center

Name of recruitment center
Shohada Tajrish hospital

Full name of responsible person
Faeghe Mollaabasi

Street address
Tajrish Sq

City
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Province
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Postal code
1989934148

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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
Velenjak, Shahriari Sq

City
Tehran

Province
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1983969411

Phone
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Email
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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 updating data

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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