Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effects of triamcinolone and bleomycin on hypertrophic scars caused by body burns

Protocol summary

Study aim
Comparison of the effects of triamcinolone and bleomycin on hypertrophic scars caused by body burns

Design
This study is a clinical trial with a control group, with parallel groups, double-blind, randomized on 35 patients. Block randomization method was used for randomization.

Settings and conduct
For each patient, two adjacent or non-adjacent areas in the body are randomly selected for intralesional injection (triamcinolone and bleomycin). The selected burn size is between 5 and 10 square centimeters. The injection site for triamcinolone and bleomycin is clearly defined so that they are not confused in future injections. The maximum dose of triamcinolone is 40 mg per course and the maximum dose of bleomycin is 10 units. The injection is performed using a #27 needle under sedation in the operating room. At the beginning of the study and at the end of the fourth month, quality photos are taken of all patients with a camera to be compared by two plastic surgeons.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Burn patients two months after recovery Exclusion criteria: Patient dissatisfaction, Hypersensitivity to triamcinolone or bleomycin

Intervention groups
Intervention group: The effect of bleomycin drug on the healing of hypertrophic scars caused by burns. Control group: The effect of triamcinolone drug on the healing of hypertrophic scars caused by burns.

Main outcome variables
Scar size, injection site pain, injection site inflammation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120410009431N4**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**
Update count: **0**

Registration date
2022-11-21, 1401/08/30

Registrant information

Name
Siamak Farokh Forghani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2220 2974

Email address
siamakfarokh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of triamcinolone and bleomycin on hypertrophic scars caused by body burns

Public title
Comparison of the effects of triamcinolone and

bleomycin on burn wounds

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Burn patients two months after recovery

Exclusion criteria:
Patient dissatisfaction Hypersensitivity to triamcinolone or bleomycin

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block 4, we divide patients into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemat Highway next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
8874113911

Approval date
2020-04-21, 1399/02/02

Ethics committee reference number
IR.IUMS.FMD.REC.1399.061

Health conditions studied

1

Description of health condition studied
burn

ICD-10 code
M61.3

ICD-10 code description
Calcification and ossification of muscles associated with burns

Primary outcomes

1

Description
Scar size

Timepoint
Four months after injection

Method of measurement
Using a ruler

2

Description
Pain in the injection area

Timepoint
After injection

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
injection site inflammation

Timepoint
After injection

Method of measurement
Observation

Intervention groups

1

Description

Intervention group: For each patient, two adjacent or non-adjacent areas in the body are randomly selected for intralesional injection (triamcinolone). The selected burn size is between 5 and 10 square centimeters. The injection site for triamcinolone is clearly defined so that they are not confused in future injections. The maximum dose of triamcinolone (manufactured by Exir company) is 40 mg per period. The injection is performed using a #27 needle under sedation in the operating room. All patients will be taken quality pictures with a camera at the beginning of the study and at the end of the fourth month to be compared by two plastic surgeons.

Category

Treatment - Drugs

2

Description

Control group:For each patient, two adjacent or non-adjacent areas in the body are randomly selected for intralesional injection (bleomycin). The selected burn size is between 5 and 10 square centimeters. The injection site for bleomycin is clearly defined so that they are not confused in future injections. The maximum dose of bleomycin (manufactured by Exir company) is 10 units per period. The injection is performed using a #27 needle under sedation in the operating room. All patients will be taken quality pictures with a camera at the beginning of the study and at the end of the fourth month to be compared by two plastic surgeons.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrate fatemeh hospital
Full name of responsible person
Siamak Farokh Forghani
Street address
16 Azar street, Keshavarz avenue
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 2220 2974
Email
siamakfarokh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hosein Keyvani
Street address
Hemat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8670 5503
Email
keyvani.h@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Siamak Farokh Forghani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
16 Azar street, Keshavarz avenue
City
Tehran
Province
Tehran
Postal code
8874113911

Phone
+98 21 8670 5503
Email
siamakfarokh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Siamak Farokh Forghani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
16 Azar street, Keshavarz avenue
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 8670 5503
Email
siamakfarokh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Siamak Farokh Forghani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
16 Azar street, Keshavarz avenue
City
Tehran
Province
Tehran
Postal code
8874113911
Phone
+98 21 2220 2974
Email
siamakfarokh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available