Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effect of Mitomycin C and triamcinolone injection on Hypertrophic scars in burn patients in Ahwaz city

Protocol summary

Study aim
Comparison of the effect of mitomycin c and triamcinolone injection on hypertrophic scars in burn patients in Ahwaz city

Design
Patients with a 1:1 ratio will be placed in two groups receiving mitomycin C with a concentration of 0.4 mg/d and triamcilonone. This study will be conducted in a triple-blind manner, so that the patients, the researcher, and the supervisor were not aware of the grouping of the patients and the medication received by them. In such a way that the drugs are completely similar in terms of shape, color, smell.

Settings and conduct
This is a clinical trial study that will be conducted in Taleghani Hospital, Ahvaz, Iran between 2022 and 2023. This study will be conducted as a three-way blind, so that the participants, the researcher, and the Data and Safety Monitoring Board (DSMB) will not know the type of intervention allocated. Finally, patients with hypertrophic burn scar complications are divided into two groups. The first group will be received mitomycin C and the second group will be received triamcilonone. After that, in a period of two months, patients will be evaluated in both places in terms of reducing the size of scar and keloid, as well as in terms of color change, vascularity, flexibility, width based on Vancouver criteria and local itching.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with burns and needing injections Exclusion criteria: • Pregnant women and nursing mothers • People with mental problems • Inability to write or read Farsi • Prisoners • People who do not want to participate in the study

Intervention groups
- Intervention group: recipient of mitomycin C with a concentration of .4 mg/d, one dose, manufactured by KOREA UNITED PHARM - Control group: Control group: Triamcinolone, 3 doses, two weeks apart for every dose, 1 mg, produced by Alborz Daru Company

Main outcome variables
Hypertrophic Scars

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230212057391N1**
Registration date: **2023-04-10, 1402/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-10, 1402/01/21**
Update count: **0**

Registration date
2023-04-10, 1402/01/21

Registrant information
Name
Jafar Jafarzade
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3332 5431
Email address
drj.jafarzadeh1983@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-20, 1401/12/01
Expected recruitment end date
2023-09-22, 1402/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Mitomycin C and triamcinolone injection on Hypertrophic scars in burn patients in Ahwaz city

Public title
Mitomycin C on Hyettrophic scars in comparison with triamcinolone injection in burn patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with burns and needing injections Patients over 18 years old

Exclusion criteria:
• Pregnant women and nursing mothers • People with mental problems • Inability to write or read Farsi • Prisoners • People who do not want to participate in the study

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
• Randomization method and description of each method: block of 4 • Randomization unit: individual • Randomization tool: Web-based randomization (https://www.sealedenvelope.com/), sealed envelope • How to make a random sequence: Randomization will be done on the web (https://www.sealedenvelope.com). After selecting Create list, it specifies the number of groups, block size and length of the list and based on that, it provides the randomization list. • Explanation of allocation concealment: Sealed envelopes that are assigned to each participant upon entering, based on which they will be placed in one of the two groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients with equal to ratio are placed in two groups receiving mitomycin C with a concentration of .4 mg/dose and triamcilonone. This study is done in a three-way blind way, so that the patient, the researcher and the observer will not have any information about which group the people will be placed in and what medicine they will receive. In this way, the medicines will be completely similar in terms of shape, color, smell. In such a way that it is not clear for the patient, the researcher and the observer who receives what medicine

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan hospital, Ahvaz University of Medical Sciences

Street address
Farvardin Blvd

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Approval date
2022-11-15, 1401/08/24

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.129

Health conditions studied

1

Description of health condition studied
Burn

ICD-10 code
T20

ICD-10 code description
Burn and corrosion of head, face, and neck

Primary outcomes

1

Description
Hypertrophic scars

Timepoint
In a period of 2 months at the beginning of the study and 2 months after the injection

Method of measurement
Measurement is done with a ruler.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: recipient of mitomycin C with a concentration of .4 mg/d, one dose, manufactured by KOREA UNITED PHARM
Category
Treatment - Drugs

2

Description
Control group: Control group: triamcilonone, 3 doses, two weeks apart for every dose, 1 mg, produced by Alborz Daru Company
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Medical Education Center, Ahvaz
Full name of responsible person
Dr Alireza Rafati
Street address
Padad Shahr, Hejrat square
City
Ahvaz
Province
Khouzestan
Postal code
61339 11151
Phone
+98 61 3554 0256
Fax
+98 61 3554 0256
Email
htaleghani@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoush Zakerkish
Street address
Iran, Ahvaz, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
+98 61 3311 0000
Fax
+98 61 3311 0000
Email
aduaum@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Abdulreza Sheikhi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Farvardin Blvd
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
009861337430011
Email
sheikhi-a@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Jafar Jafarzadeh
Position
Resident
Latest degree
Specialist

Other areas of specialty/work
General Surgery
Street address
Ahvaz, Taleghani Hospital
City
Ahvaz
Province
Khouzestan
Postal code
61339 11151
Phone
+98 61 3554 0256
Email
drj.jafarzadeh1983@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Jafar Jafarzadeh
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
Ahvaz, Taleghani Hospital
City
Ahvaz
Province
Khouzestan
Postal code
61339 11151
Phone
+98 61 3554 0256
Email
drj.jafarzadeh1983@gmail.com

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
Only the results related to the outcome and output of the intervention can be published. It is provided to researchers for further research.
When the data will become available and for how long
The data will be available after the publication of the article.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
In meta-analysis studies and conducting similar studies
From where data/document is obtainable
Refer to the Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences. While submitting the proposal and obtaining the code of ethics from the ethics committee of this university, access to the data should be provided for the researchers.
What processes are involved for a request to access data/document
Researchers can have access to data through correspondence with the vice president of research and technology of the university and since obtaining the code of ethics from the research ethics committee of Ahvaz University of Medical Sciences.
Comments