

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Ahvaz

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Postal code

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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

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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

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

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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

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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Email

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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

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