

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Comparison of the efficacy of topical silver sulfadiazine-cerium nitrate with silver sulfadiazine cream in in treatment of moderate and severe burns

#### Protocol summary

##### Study aim

Comparison of the efficacy of topical silver sulfadiazine-cerium nitrate with silver sulfadiazine cream in in treatment of moderate and severe burns

##### Design

Randomized, single blind, superiority, parallel group trial

##### Settings and conduct

112 patients with burns in 2 and 3 degree referred to burn section of Imam Reza Hospital in Mashhad were randomly divided into two groups of silver sulfadiazine alone (56 patient) or silver sulfadiazine-cerium nitrate (56 patients) based on a four-block randomized blockade. Silver sulfadiazine cream 1% will be prepared from commercially available products and silver sulfadiazine-cerium nitrate (1% and 2.2%) will be formulated in Mashhad Pharmacy Industrial Laboratory. All patients receive appropriate fluid and electrolyte and will be recorded after performing epithelialization rate assessment. 90% re-epithelialization will be considered as a complete repair. The overall response to treatment will be determined by the outcome of the wound culture and the duration of skin epithelization or preparation for the transplant.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Second and third degree burns based on the Laund & criterion. 2.Minimum burn rate of patients is 10% and maximum of 50% 3.Age 18-70 years

##### Intervention groups

In the intervention group: The topical therapy with the formulation of silver sulfadiazine-cerium nitrate 2.2% as long as the relative thickness of the burn is completely cured In standard group: daily use of silver sulfadiazine topical formulation

##### Main outcome variables

Primary outcomes: The Re-epithelialization rate based on number of days (90% re-epithelialization will be considered as a complete repair). secondary outcome:

pain assessment based on visual pain manual scale, duration of hospitalization and infection frequency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190927044902N1**

Registration date: **2020-01-05, 1398/10/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-05, 1398/10/15**

Update count: **0**

##### Registration date

2020-01-05, 1398/10/15

##### Registrant information

##### Name

Emad Molaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3881 8478

##### Email address

molaeie942@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-22, 1398/07/30

##### Expected recruitment end date

2021-02-18, 1399/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the efficacy of topical silver sulfadiazine-cerium nitrate with silver sulfadiazine cream in in treatment of moderate and severe burns

**Public title**  
Effect of topical silver sulfadiazine-cerium nitrate in treatment of moderate to severe burn

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Second and third degree burns according to Lund & Browder criteria Minimum burn rate of patients is 10% and maximum of 50% Patients are being hospitalized in the first 24 hours of a hospital bed. informed consent to enter the study .

**Exclusion criteria:**  
Inhalation burn Electrical and chemical burns Burns on face and hands and perineum A history of known allergies to sulfonamides History of Methemoglobinemia Pregnancy and lactation G6PD deficiency Oliguria and Anuria Functional liver disorders Lack of satisfaction with the patient to enter or continue intervention

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: **112**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
simple randomization with randomization list prepared from site randomization.com

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The patient, the treating physician and the evaluator are due to the different appearance of the formulation on the wound aware of the type of formulation (cerium nitrate will have a yellow-green appearance that produces a relatively dry scar while Silver sulfadiazine produces a damp matrix scar). They cannot be blind to the type of treatment. But the data analyzer will remain unaware of the grouping of patients until the end of the analysis.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Ghoreishi Building, Daneshgah Street, Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91357345

#### Approval date

2019-09-20, 1398/06/29

#### Ethics committee reference number

IR.MUMS.REC.1398.172

## Health conditions studied

### 1

#### Description of health condition studied

Burns and corrosions

#### ICD-10 code

T29.0

#### ICD-10 code description

Burn of unspecified body region, unspecified degree

## Primary outcomes

### 1

#### Description

90% Re-epithelialization as complete restoration

#### Timepoint

7, 14, 21 and 28 days after onset of treatment with formulation

#### Method of measurement

The Re-epithelialization rate will also be recorded as very slow (5-6 weeks), slow (about 4 weeks), moderate (2-3 weeks), or fast (about 10 days).

## Secondary outcomes

### 1

#### Description

The pain of the patient

#### Timepoint

once every three days

#### Method of measurement

The use of the visual pain criterion will be evaluated and will be graded from 0-10

## 2

### **Description**

Duration of hospitalization

### **Timepoint**

Every 5 days

### **Method of measurement**

Based on the percentage of grafts taken on day 5

## 3

### **Description**

Infection frequency

### **Timepoint**

Every week

### **Method of measurement**

Wound culture

## **Intervention groups**

### 1

#### **Description**

control group: daily application of topical formulation of silver sulfadiazine, and closed dressing.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: daily application of topical treatment with silver sulfadiazine formulation with cerium nitrate and closed dressing.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza hospital, affiliated to Mashhad University of Medical Sciences

##### **Full name of responsible person**

Sepideh Elyasi

##### **Street address**

School of Pharmacy, Ferdowsi University campus, Vakil Abad Blvd., Mashhad

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

17871 91886

##### **Phone**

+98 51 3180 1588

##### **Email**

elyasis@mums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Mohsen Tafaghodi

##### **Street address**

School of Pharmacy, Ferdosi University Campus, Vakil Abad Blv., Mashhad, Iran

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tafaghodim@mums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Emad Molaie

##### **Position**

Pharm D student

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Medical Pharmacy

##### **Street address**

School of Pharmacy, Ferdosi University Campus, Vakilabad Blvd., Mashhad, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Sepideh Elyasi

**Position**

استادیار

**Latest degree**

Ph.D.

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مشهد، بولوار وکیل آباد، دانشگاه فردوسی، دانشکده داروسازی

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Emad Molaei

**Position**

Pharm D student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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**Postal code**

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**Email**

Molaeie942@mums.ac.ir

## 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

Undecided - It is not yet known if there will be 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

No - There is not 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

The mentioned data will be published in an article after the completion of the study.

### When the data will become available and for how long

The information will be available in article for ever.

### To whom data/document is available

any one who want

### Under which criteria data/document could be used

Unpublished data will be accessible after agreement of all contributors and also research deputy of Mashhad University of Medical Sciences.

### From where data/document is obtainable

Mail to the corresponding author

### What processes are involved for a request to access data/document

The request should be discussed with all contributors of the study and research deputy of Mashhad University of Medical Sciences.

### Comments