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 Laund & 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
City
Mashhad
Province
Razavi Khorasan
Postal code
17871 91886
Phone
+98 51 3180 1337
Email
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 Molaei
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
City
Mashhad
Province
Razavi Khorasan
Postal code

17871 91886

Phone
+98 51 3180 1588

Email
Molaeie942@mums.ac.ir

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.

Other areas of specialty/work
Medical Pharmacy

Street address
مشهد، بولوار وکیل آباد، دانشگاه فردوسی، دانشکده داروسازی

City
مشهد

Province
Razavi Khorasan

Postal code
17871 91886

Phone
+98 51 3180 1588

Email
elyasis@mums.ac.ir

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

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

City
Mashhad

Province
Razavi Khorasan

Postal code
17871 91886

Phone
+98 51 3180 1337

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