

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the therapeutic effect of amniotic membrane dressing with silver sulfadiazine ointment dressings in the management of superficial burns wounds, second degree of trunk and limb Ayatollah in Mousavi Hospital of Zanjan in 2016-2017

Protocol summary

Summary

The overall objective of the project: to determine the treatment effect compared amniotic membrane dressing with silver sulfadiazine ointment dressings in superficial second degree burn wounds. Study design: Randomized Clinical Trial. Inclusion criteria: all patients with superficial thermal burns grade 2 less than 20% and no burns isolated to the head and neck; lack of burn areas genitalia; stable vital signs; no history of psychiatric disorders in patients with burns; the absence of drug and psychotropic; smoking, no history of heart, kidney and liver problems; no diabetes; no history of malnutrition; not taking corticosteroids or drugs that suppress the immune system; lack of burns inhalation; no history for sulfonamides toxicity; no previous burns in the recent burn site; no evidence of infection in burns and age over 18 years in patients presenting to the emergency department or clinic. Exclusion criteria: allergic reaction to silver sulfadiazine ointment; side effects or sensitivity to amniotic membrane dressing; requirement to wound debridement in the operating room. Sample size: The formula seems adequate number of patients in each group of 18 people but we have 25 patients in each group (groups) will be studied. Intervention: in the intervention group burn used dressing with amniotic membrane. In the control group burn used dressing with Gauze soaked with silver sulfadiazine ointment. Intervention period: one month. Result of studied: the pain and analgesic consumption and the amount of scarring and infection; wound healing and dressing; and the cost and number of days of hospitalization in hospital has been compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110824947N1**

Registration date: **2017-02-06, 1395/11/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-06, 1395/11/18

Registrant information

Name

Mehran Salehian

Name of organization / entity

Department of surgery, Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of amniotic membrane dressing with silver sulfadiazine ointment dressings in the management of superficial burns wounds, second degree of trunk and limb Ayatollah in Mousavi Hospital of Zanjan in 2016-2017

Public title

Burn dressing with amniotic membrane

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients wit; superficial thermal burns grade 2 less than 20% and no burns isolated to the head and neck; lack of burn areas genitalia; stable vital signs; no history of psychiatric disorders in patients with burns; the absence of drug and psychotropic; smoking, no history of heart, kidney and liver problems; no diabetes; no history of malnutrition; not taking corticosteroids or drugs that suppress the immune system; lack of burns inhalation; no history for sulfonamides toxicity; no previous burns in the recent burn site; no evidence of infection in burns and age over 18 years in patients presenting to the emergency department or clinic. Exclusion criteria: allergic reaction to silver sulfadiazine ointment; side effects or sensitivity to amniotic membrane dressing; requirement to wound debridement in the operating room.

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi blvd.

City

Zanjan

Postal code

Approval date

2016-12-20, 1395/09/30

Ethics committee reference number

IR.ZUMS.REC.1395.226

Health conditions studied

1

Description of health condition studied

Degree 2 burn wounds

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Epithelialization

Timepoint

Seven days, 14 days and 30 days after intervention (dressing with amniotic membrane)

Method of measurement

Based on the physical examination

2

Description

Wound infection

Timepoint

Daily visits during hospitalization and based on clinical evidence and cultivation of bending if positive clinical evidence (fever, discharge and cellulite)

Method of measurement

Clinical descriptions of daily visits

3

Description

Analgesia Consumption

Timepoint

Daily during admission

Method of measurement

Medical records

4

Description

Frequency of dressing exchange

Timepoint

From first until 30th day of the study

Method of measurement

The number of dressing exchange

Secondary outcomes

1

Description

Wound scar

Timepoint

30 days after the intervention

Method of measurement

Physical examination (0 = no scar; 1 = mild ; 2 = moderate ; 3 = severe

2

Description

Pain

Timepoint

The seventh day after the intervention (dressing with amniotic membrane or silver sulfadiazine ointment)

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

In the intervention group burns area are dressing with amniotic membrane

Category

Treatment - Other

2

Description

In the control group burns area are dressing with gauze soaked with silver sulfadiazine ointment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi hospital

Full name of responsible person

Dr. Mehran Salehian

Street address

Mousavi hospital, Gavazng road

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi blvd.

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Mehran Salehian

Position

MD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

General Surgeon

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Full name of responsible person

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City

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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty