Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of dressing of 1% silver sulfadiazine cream with combination of 10% Betadine and 1% Acetic Acid in the management of Deep Partial-Thickness (Deep Second-Degree) Burn Wounds

Protocol summary

Study aim

Comparison of dressing of 1% Silver sulfadiazine cream with combination of 10% Betadine and 1% Acetic Acid in the management of Deep Second-Degree burn wounds

Design

In this study, 60 patients with Deep Second-Degree burn between 5 to 20 percent total burn surface area was selected, randomly assigned to two groups of Silversulfadiazine cream and Acetic acid and Betadine solution. Dressing is done daily.

Settings and conduct

The site of the study is the Burn Departmant of Imam Reza Hospital in Mashhad. In both groups, pain intensity and colonization and wound infection and wound preparation for grafting are checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Dęgenerative Deep Second-Degree burns between 5% and 20%; From the time the burns up to the time of entry into the study is not more than 6 hours; There are no underlying diseases and immune systems like diabetes, cancer, AIDS, hypertension, cardiovascular disease and peripheral neuropathy; The patient has no skin allergies; Be alert and able to answer questions; The absence of symptoms of infection in the wound and lack of colonization on the first day of admission; Exclusion Criteria:Age is more than 50 years old; Age is less than 15 years old; Electrical burns; Chemical burns;Inhaler burn

Intervention groups

Intervention group 1: After wound washing, they are daily dressed with silver sulfadiazine 1% cream (1.5 mm thick on the wound). Intervention group 2: After washing the wound daily, soaked in a solution of sterile gas to a combination of Betadine 10% and 1% acetic acid with the same volume used for dressing wounds

Main outcome variables

Variables: pain by visual analogue scale, wound colonization by culture using a sterile swab, wound infection, localized infection by Check List of clinical assessment, prepare for grafting with the creation of granulation tissue in the wound checked

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171023036962N1**
Registration date: **2018-05-04, 1397/02/14**
Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**
Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

saberih5@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-11-06, 1396/08/15

Actual recruitment end date
2018-03-11, 1396/12/20
Trial completion date
empty

Scientific title
Comparison of dressing of 1% silver sulfadiazine cream with combination of 10% Betadine and 1% Acetic Acid in the management of Deep Partial-Thickness (Deep Second-Degree) Burn Wounds

Public title
Comparison of dressing of 1% silver sulfadiazine cream with combination of 10% Betadine and 1% Acetic Acid in the management of Deep Partial-Thickness (Deep Second-Degree) Burn Wounds
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Degenerative Deep Partial-Thickness (Deep Second-Degree) burns between 5% and 20% From the time the burns up to the time of entry into the study is not more than 6 hours There are no underlying diseases and immune systems like diabetes, cancer, AIDS, hypertension, cardiovascular disease and peripheral neuropathy (neuropathy). The patient has no skin allergies Be alert and able to answer questions
Exclusion criteria:
Age is more than 50 years old Age is less than 15 years old
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
60 numbers are given to SPSS software, and the software randomly divides the numbers into two groups and patients enter the groups according to the time of entry into the study
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
Ethics committee of Mashhad University of Medical Sciences
Street address
Building Qureshi, University Avenue, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Approval date
2018-02-14, 1396/11/25
Ethics committee reference number
IR.MUMS.REC.1396.252

Health conditions studied

1

Description of health condition studied
management of Deep Partial-Thickness (Deep Second-Degree) Burn Wounds
ICD-10 code
T 30.2
ICD-10 code description
Burn of second degree, body region unspecified

Primary outcomes

1

Description
Pain
Timepoint
Before and after dressing - Day 1 and 3, 7 and 10
Method of measurement
Visual Analogue Scale

2

Description
Infection
Timepoint
Daily after opening the dressing
Method of measurement
Clinical checklist for localized infection of burn wound

3

Description
Clonization
Timepoint
Days 1, 3, 7 and 10
Method of measurement
Send the sterile swab specimen to the microbiological laboratory

Secondary outcomes

1

Description
Prepare the wound for graft
Timepoint
Daily after opening the dressing
Method of measurement
The creation of granulation tissue in the wound area

Intervention groups

1

Description
Intervention group: After wound washing, they are daily dressed with silver sulfadiazine 1% cream (1.5 mm thick on the wound).
Category
Treatment - Drugs

2

Description
Intervention group: After washing the wound daily, soaked in a solution of sterile gas to a combination of Betadine 10% and 1% acetic acid with the same volume used for dressing wounds
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Nursing and Midwifery
Full name of responsible person
Hossein saberi
Street address
Faculty of Nursing and Midwifery, Ibn-Sina Avenue, Crossroads Doktora, Daneshgah Avenue, Mashhad, Khorasan razavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
Hamid Chamanzari
Position
Master of Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
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Master

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Postgraduate Nursing Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available