

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Department 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: Degenerative 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3852 8513

Fax

+98 51 3852 8513

Email

saberih5@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

Mashhad, University Avenue, Building Qureshi

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3852 8513

Fax

+98 51 3852 8513

Email

saberih5@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

Hamid Chamanzari

Position

Master of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Ibn-sina Avenue, Crossroads Doktora

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 1511

Email

chamanzarih@mums.ac.ir

Person responsible for scientific 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

Street address

Faculty of Nursing and Midwifery, Ibn-Sina Avenue,
Crossroads Doktora

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 1511

Email

chamanzarih@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Saberi

Position

Postgraduate Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Ibn-Sina Avenue,
crossroads Doktora

City

mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Fax

+98 51 3859 1511

Email

saberih5@mums.ac.ir

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