

# 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

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9137913199

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+98 51 3852 8513

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##### 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

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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

##### Street address

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

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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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

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**Email**

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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