

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

#### Protocol summary

##### Study aim

Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

##### Design

Clinical trial, double-blind with parallel groups, randomized, in phase 3, 40 patients will be selected as available and allocated by permutation blocks method.

##### Settings and conduct

The place of intervention was the emergency department of Bohloul hospital. For the sesame oil group, first, the wound area will be washed with sodium chloride and exposed to the open air for 5 minutes until it dries completely. Then, the wound area is smeared with 2 ml of sesame oil (for 10 square centimeters of the wound) and the surface of the wound is covered with freezer plastic and then it will be bandaged. For the silver ointment group, all the above steps have been done and the wound will be dressed with 1% silversulfadiazine ointment. At the end, the diagnosis of wound healing will be confirmed by a specialist. The emergency medicine physician and the data analyst will be unaware of the patient grouping.

##### Participants/Inclusion and exclusion criteria

Informed consent to participate in the study Age 20-60 years First and second degree burns with an extent of 1-10% Burns due to contact with a heat source or liquids Less than 6 hours passed from the time of the burn to the time of going to the treatment center Hemoglobin and total protein normal Absence of underlying diseases such as anemia, diabetes, cardiovascular diseases, malignancy and immune system deficiency Not taking painkillers and NSAIDs orally or topically until the first visit to the treatment center Confirmation by the doctor that the patient does not need to be hospitalized Not allergic to sesame oil

##### Intervention groups

Dressing group with sesame oil, will be dressed with sesame oil. Dressing group with 1% silver sulfadiazine

ointment, will be dressed with silver ointment.

##### Main outcome variables

Healing & scars

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180221038821N5**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

##### Registration date

2023-02-05, 1401/11/16

##### Registrant information

##### Name

Iman Ghorbany Moghaddam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5722 0576

##### Email address

ghorbani.i@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-21, 1401/11/01

##### Expected recruitment end date

2023-07-23, 1402/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

**Public title**  
Comparison of the effect of sesame oil and 1% silver sulfadiazine ointment on the pain, healing and scarring of burn wounds

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Informed consent to participate in the study Age 20-60 years First and second degree burns with an extent of 1-10% Burns due to contact with a heat source or liquids  
**Exclusion criteria:**  
Sesame oil allergy Confirmation of the need for hospitalization of the patient by the doctor Taking painkillers and NSAIDs orally or topically until the first visit to the treatment center Background diseases such as anemia, diabetes, cardiovascular diseases, malignancy and immune system defects Abnormal hemoglobin and total protein More than 6 hours passed from the time of the burn to the time of going to the medical center

**Age**  
From **20 years** old to **60 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients were first selected by the available method and then divided into two groups of sesame oil and silver ointment by using 4 permutation blocks. In this method, the sesame oil group was coded with the letter A and the silver ointment group was coded with the letter B. The six possible states in the blocks included ABAB, BBAA, AABB, BABA, AAAA, BBBB, and each block was assigned a number. For every four selected people, a number will be selected according to the list, and people will be assigned to two groups of sesame oil and silver ointment in this way.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The emergency medicine doctor who will confirm the recovery of the patients will not know about the grouping of the patients. The data analyst will also be unaware of

the grouping of patients.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethical Committee of Gonabad University of Medical Sciences

**Street address**  
Asian Road Rim, Gonabad University of Medical Sciences

**City**  
Gonabad

**Province**  
Razavi Khorasan

**Postal code**  
96916-47161

**Approval date**  
2022-12-24, 1401/10/03

**Ethics committee reference number**  
IR.GMU.REC.1401.137

## Health conditions studied

**1**

**Description of health condition studied**  
Burn

**ICD-10 code**  
Z73.0

**ICD-10 code description**  
Burn-out

## Primary outcomes

**1**

**Description**  
Wound healing time

**Timepoint**  
After confirming the healing of the wound by an emergency medicine specialist

**Method of measurement**  
Questionnaire (Day)

**2**

**Description**  
The scar left by the wound

**Timepoint**  
After confirming the healing of the wound by an

emergency medicine specialist

#### Method of measurement

Beitz-Johnson Burn Wound Assessment Tool

## Secondary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

Before and after dressing in the first session

#### Method of measurement

Visual pain scale

## Intervention groups

### 1

#### Description

Intervention group: Sesame oil group: For the sesame oil group, the burn wound dressing with sesame oil will first be washed with sodium chloride for washing and exposed to the open air for 5 minutes until it dries completely. Then, the wound area is smeared with 2 ml of sesame oil (for 10 square centimeters of the wound) and the surface of the wound is covered with freezer plastic (to absorb more sesame oil) and then it will be bandaged. Sesame oil used in this notice will be completely natural and without preservatives with standard devices from a local store and will be prepared under supervision. It should be noted that this extract is 100% oily and in addition to being free of water molecules, it also contains antimicrobial compounds that prevent the growth of microbial agents in this extract. Nevertheless, in order to ensure the negativity of the microbial culture, random samples of the extract prepared in the microbial culture media of blood agar, chocolate agar, eosin methylene blue, Kant agar plate, lauryl sulfate broth and selected culture media for the investigation of yeasts and fungi will be used.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Silversulfadiazine 1% group: Dressing the burn wound first, the wound area will be washed with normal saline for washing and exposed to the open air for 5 minutes until it dries completely. Then the wound will be smeared with 1% silver sulfadiazine ointment and covered with freezer plastic and bandaged. One percent silver sulfadiazine ointment of Iran Najo Pharmaceutical Company will also be used for this group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Allameh Bohlol Hospital, Gonabadi

##### Full name of responsible person

Dr. Mehdi Pasban

##### Street address

Parastar Blvd

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 0576

##### Email

info@gmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Dr. Mohammadreza Mansourian

##### Street address

Asian Roads, Gonabad University of Medical Sciences, Student Research Committee

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 0576

##### Email

info@gmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gonabad 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**

Gonabad University of Medical Sciences

**Full name of responsible person**

Iman Ghorbany Moghaddam

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No9, Behesht Street, Emam Sajjad Blvd, Gonabad  
Town

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691647161

**Phone**

+98 51 5722 0576

**Fax****Email**

imanghorbany135213@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Dr. Moosa Sajjadi

**Position**

Head of the Center for the Study and Development of  
Medical Sciences Education

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Asian Roads, Gonabad University of Medical Sciences

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 0576

**Email**

sajjadi1975@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Iman Ghorbany Moghaddam

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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