

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of the effect of Swalin ointment and 1% Silver sulfadiazine on the repair of 2nd degree deep burns

#### Protocol summary

##### Study aim

Comparison of the effect of Swalin ointment and 1 Silver sulfadiazine on the repair of 2nd degree deep burns

##### Design

A randomized, single-blind, interventional, control group clinical trial, phase 3 on 82 patients. The randomization tool of this study is Excel software and this software is also used to create a random sequence.

##### Settings and conduct

Patients with deep 2nd degree burns who refer to Shahid Motahari Burn Hospital in Tehran during the study, if they are eligible, will be included in the study and will be randomly assigned to the intervention and control groups using the random block method. This study will be conducted in a double-blind manner, so that the patients and the doctor examining the patients will not know the type of intervention.

##### Participants/Inclusion and exclusion criteria

Age 15-45 years, deep 2nd degree thermal burn wound of the body less than 10% in total, good general condition and no underlying disease such as diabetes, no history of autoimmune diseases, no HIV infection, no history of taking immunosuppressive drugs, No history of immune system deficiency, no history of hospitalization in the psychiatric ward, no history of burns. Conditions for not entering the study: other types of burns such as chemical, electrical, etc., wound stained with polluting substances, use of any substance other than drinking water on the wound before entering the study, untreated active infection in different parts body, patients with underlying diseases and immune system defects such as cancer, AIDS, diabetes, high blood pressure, etc., burns on the face and genital areas, pregnant and lactating women.

##### Intervention groups

In the first group of patients with deep 2nd degree burns and treated with 1% silver sulfadiazine ointment, and in the second group of patients with deep 2nd degree burns and treated with Swalin ointment.

#### Main outcome variables

The size of the burn surface

#### General information

##### Reason for update

##### Acronym

Swalin (SW) Silver Sulfadiazine (SSD)

##### IRCT registration information

IRCT registration number: **IRCT20220702055349N1**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **prospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

##### Registration date

2022-11-05, 1401/08/14

##### Registrant information

##### Name

Mehrdad Bakhtiyari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8862 2689

##### Email address

mehr\_bakhtiyari@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-21, 1401/08/30

##### Expected recruitment end date

2023-05-21, 1402/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of Swalin ointment and 1% Silver sulfadiazine on the repair of 2nd degree deep burns

**Public title**  
Comparison of the effect of Swalin ointment and 1% silver sulfadiazine on deep 2nd degree burns

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 15-45 years, 2nd degree thermal burn wound of 1% to 2% depth of the body, less than 24 hours have passed since the burn, good general condition and no pregnancy, no underlying disease such as diabetes, no history of autoimmune diseases, No HIV infection, no immune system deficiency, no history of taking immunosuppressant drugs, no history of psychiatric disorders, no history of electrical chemical thermal burns, no history of allergies and sensitivities.  
**Exclusion criteria:**  
Other types of burns, such as chemical, electrical, etc., wound stained with polluting substances, using any substance other than drinking water on the wound before entering the study, untreated active infection in different parts of the body, patients with underlying diseases and immune system defects such as cancer, AIDS, diabetes, high blood pressure, etc., burns on the face and genital areas, pregnant and lactating women,

**Age**  
From **15 years** old to **45 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **82**

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

**Randomization description**  
Randomization in this study is done through block randomization with 6 blocks. The randomization unit is an individual type. The randomization tool of this study is Excel software and this software is also used to create a random sequence. For concealment, an experienced person who is not one of the project collaborators, in a separate center after registering the participants' information, defines the ointment code separately for each patient and informs the research team about the corresponding code.

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

**Blinding description**

In this study, the researcher, doctor and data analyst, who is responsible for collecting information, do not know the type of drug used, all patients are fully informed about the type of ointment used, and a written consent form is completed for each of them, and all treatment steps are also It will be under the supervision of the center's specialist doctor.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۳۴۹۶۱۴۵۳۵

#### Approval date

2022-10-15, 1401/07/23

#### Ethics committee reference number

IR.IUMS.FMD.REC.1401.373

## Health conditions studied

### 1

#### Description of health condition studied

Burns

#### ICD-10 code

T22

#### ICD-10 code description

Burn and corrosion of shoulder and upper limb, except wrist and hand

### 2

#### Description of health condition studied

Burns

#### ICD-10 code

T23

#### ICD-10 code description

Burn and corrosion of wrist and hand

### 3

#### **Description of health condition studied**

Burns

#### **ICD-10 code**

T24

#### **ICD-10 code description**

Burn and corrosion of lower limb, except ankle and foot

### 4

#### **Description of health condition studied**

Burn

#### **ICD-10 code**

T25

#### **ICD-10 code description**

Burn and corrosion of ankle and foot

## **Primary outcomes**

### 1

#### **Description**

The size of the burn surface

#### **Timepoint**

Days 1, 7, 14, 21 and 28

#### **Method of measurement**

Photo image using imagej software

## **Secondary outcomes**

### 1

#### **Description**

Angiogenesis factors

#### **Timepoint**

fourteenth day

#### **Method of measurement**

ELISA assay

### 2

#### **Description**

Inflammatory factors

#### **Timepoint**

Days 3, 7 and 14

#### **Method of measurement**

ELISA assay

### 3

#### **Description**

The amount of collagen

#### **Timepoint**

fourteenth day

#### **Method of measurement**

Masson's Trichrome Stain

### 4

#### **Description**

Number of vascular sections

#### **Timepoint**

fourteenth day

#### **Method of measurement**

H&E Staining

### 5

#### **Description**

Epithelialization

#### **Timepoint**

fourteenth day

#### **Method of measurement**

H&E Staining

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients with deep 2nd degree burns and treated with Swalin ointment

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Patients with deep 2nd degree burns and treated with 1% silver sulfadiazine ointment

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Motahari Burns Hospital of Tehran

##### **Full name of responsible person**

Mehrdad Bakhtiyari

##### **Street address**

Shahid Motahhari Burn Hospital, Rashid-Yasemi Ave, Valieasr Ave, Tehran, Iran.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

۱۹۹۶۷۱۴۳۵۳

##### **Phone**

+98 21 8877 0031

##### **Email**

hospital.motahari@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Mehrdad Bakhtiyari

**Street address**

Iran University of Medical Sciences, Hemat Highway,  
next to Milad Tower, Tehran

**City**

tehran

**Province**

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**Postal code**

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**Phone**

+98 21 8670 1021

**Email**

info@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mehrdad Bakhtiyari

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Anatomy

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**Postal code**

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mehr\_bakhtiyari@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hamidreza Alizadeotaghvar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Plastic & Reconstructive Surgery

**Street address**

Shahid Motahhari Burn Hospital, Rashid-Yasemi Ave,  
Valieasr Ave, Tehran, Iran.

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**Postal code**

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021-88770031-36

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drhralizade@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mahdi Heydari

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Anatomy

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**City**

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**Province**

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**Postal code**

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**Phone**

+98 21 8862 2689

**Email**

Mahdiheydari438@yahoo.com

## 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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available