

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison the Effects of Silver Sulfadiazine Ointment and Adibderm Herbal Ointment in Treatment of Patients with Grade II Dermal burns admitted to the Emergency Department

#### Protocol summary

##### Summary

1) Objectives: This research will be accomplished with the purpose of the effect of Adibderm herbal ointment on treatment of grade II dermal burning injuries in Emergency department 2) Design: 60 patients with grade II dermal burning injury will be divided two groups [Adibderm (group 1), Silver sulfadiazine (group 2)] with use Random Allocation Software. 3) Setting and conduct: After obtain the informed consent, severity, location and cause of burning and demographic information of patients will be registered. Then patient will be treated based on group number (1 or 2). 4) Participants including major eligibility criteria: inclusion criteria: All grade II, and 1-10% dermal burning injury 18-65 years old patients, burning with hot fluid or fire, time interval between injury and admission to the emergency room less than 6 hours. Exclusion criteria: Grade I, III, and IV burning injury, admission required to hospital ward, pregnant patients, chemical burning, face and neck and perineal burning, any underlying disease causing impaired healing (e.g. immunodeficiency, diabetes, anemia, cancer, cytotoxic drugs and allergic skin disease), dissatisfaction to participate to study. 5) Intervention: Type of treatment used in two groups are different. In group one Adibderm herbal ointment, and in group two silver sulfadiazine ointment will be used. 6) Main outcome measures variables: Healing time will be compared in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062912592N2**

Registration date: **2015-09-11, 1394/06/20**

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

Last update:

Update count: **0**

##### Registration date

2015-09-11, 1394/06/20

##### Registrant information

###### Name

Farzad Rahmani

###### Name of organization / entity

Tabriz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3335 2078

###### Email address

rahmanif@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2015-10-22, 1394/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the Effects of Silver Sulfadiazine Ointment and Adibderm Herbal Ointment in Treatment of Patients with Grade II Dermal burns admitted to the Emergency Department

##### Public title

Effect of Adibderm Herbal Ointment on Dermal Burning Injury Treatment

## Purpose

Treatment

## Inclusion/Exclusion criteria

inclusion criteria: All grade II, and 1-10% dermal burning injury 18-65 years old patients; burning with hot fluid or fire; time interval between injury and admission to the emergency room less than 6 hours. Exclusion criteria: Grade I, III, and IV burning injury; admission required to hospital ward; pregnant patients; chemical burning; face and neck and perineal burning; any underlying disease causing impaired healing (e.g. immunodeficiency, diabetes, anemia, cancer, cytotoxic drugs and allergic skin disease); dissatisfaction to participate to study.

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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 Tabriz University of Medical Sciences

##### Street address

Golgasht Street, Tabriz University of Medical Sciences

##### City

Tabriz

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

TBZMED.REC.1394.491

## Health conditions studied

### 1

#### Description of health condition studied

Burning

#### ICD-10 code

X00, X01,

#### ICD-10 code description

Exposure to smoke, fire and flames

## Primary outcomes

### 1

#### Description

Wound healing

#### Timepoint

Daily

#### Method of measurement

Emergency medicine specialist opinion

### 2

#### Description

Patient satisfaction

#### Timepoint

After the end of treatment, we will ask from patient about satisfaction of treatment

#### Method of measurement

Visual Analog Scale. This scale contains 1-10 scores that score 1 shows dissatisfaction and score 10 show excellent satisfaction

## Secondary outcomes

### 1

#### Description

Treatment complication

#### Timepoint

Daily

#### Method of measurement

Emergency medicine specialist opinion

## Intervention groups

### 1

#### Description

Intervention group 1: In this group, adibderm herbal ointment ( Danakasian company, Adib Eksir Pharmaceutical company, Khorramabad, IR Iran) based on instruction, will be used for burning injury dressing.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 1: In this group, silver sulfadiazine ointment ( Flamexin, Sina daru pharmaceutical company, Tehran, IR Iran) based on instruction, will be used for burning injury dressing.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hospital, Tabriz

**Full name of responsible person**

Farzad Rahmani

**Street address**

Azadi Avenue, Sina Hospital, Emergency Department

**City**

Tabriz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammadreza Rashidi

**Street address**

Golgashat Street, Tabriz University of Medical Sciences

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farzad Rahmani

**Position**

Assistant Professor / Emergency Medicine Specialist

**Other areas of specialty/work****Street address**

Azadi Avenue, Sina Hospital, Emergency Department

**City**

Tabriz

**Postal code****Phone**

+98 41 3549 8144

**Fax****Email**farzadrhn88@gmail.com, farzadrhn@yahoo.com,  
rahmanif@tbzmed.ac.ir**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farzad Rahmani

**Position**

Assistant Professor / Emergency Medicine Specialist

**Other areas of specialty/work****Street address**

Azadi Avenue, Sina Hospital, Emergency Department

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**Fax****Email**farzadrhn88@gmail.com, farzadrhn@yahoo.com,  
rahmanif@tbzmed.ac.ir**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol**

*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*