

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

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Golgasht Street, Tabriz University of Medical Sciences

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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

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Position

Assistant Professor / Emergency Medicine Specialist

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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