

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of Silversulfadiazine topical cream containing Epidermal growth factor (EGF) and Silversulfadiazine topical cream without Epidermal growth factor (EGF) on burn wounds healing (type II).

Protocol summary

Study aim

Main goal of this study is to assess the efficacy of Epidermal Growth Factor on burn wounds grade II in comparison with standard treatment. The objectives are comparison of wound healing rate, evaluation of dermis and epidermis thickness to compare the quality of healing and comparison of wound dimensions after treatment.

Design

A clinical trial is performed with the control group, parallel groups, double-blind, randomized, on 35 patients with two samples (wounds on body parts).

Settings and conduct

Participants receive a package containing creams. They receive the same prescription for both creams. They will use cream with label number one for area one and cream with label number 2 for area 2. Both areas are cleansed every 12 hours with normal saline, the control area is treated with topical silver sulfadiazine cream and is covered with sterile gauze. For the intervention group, 1% silver sulfadiazine topical cream containing epidermal growth factor is used and is covered with sterile gas.

Participants/Inclusion and exclusion criteria

Admission requirements: Age 18-60 years; second-degree burns, bilateral, on both hands or feet, etc.; willingness to participate in the study. Exclusion criteria: Any underlying diseases that interfere with wound healing, such as chronic kidney disease, diabetes, liver disease, and any immunodeficiency disease or smoking; having any type of cancer or history of cancer; any allergy to recombinant epidermal growth factor, silver sulfadiazine or any substance in the formulation.

Intervention groups

Two burn areas per person are randomly assigned to zones 1 or 2, and each area will receive one treatment (silver sulfadiazine cream for the control area and silver

sulfadiazine cream containing EGF for the intervention area).

Main outcome variables

Wound size; Epidermis thickness; Dermis thickness; Speed of wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054633N1**

Registration date: **2022-06-06, 1401/03/16**

Registration timing: **prospective**

Last update: **2022-06-06, 1401/03/16**

Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Majid Golkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-10, 1401/03/20

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Silversulfadiazine topical cream containing Epidermal growth factor (EGF) and Silversulfadiazine topical cream without Epidermal growth factor (EGF) on burn wounds healing (type II).

Public title

The efficacy assessment of Silversulfadiazine topical cream containing Epidermal growth factor (EGF) on burn wounds healing (type II)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with grade II burn wounds. Burn area must be bilateral, in 2 hands or 2 legs, etc.

Exclusion criteria:

Having any underlying diseases that interfere with wound healing such as chronic kidney disease, diabetes, liver disease, any diseases of immunodeficiency, and smoking. Having cancer or background of Cancer Allergy to Epidermal Growth Factor, silver sulfadiazin or any material in the formulation. Pregnancy Breastfeeding

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **35**

More than 1 sample in each individual

Number of samples in each individual: **2**

Participants have bilateral grade II burns. One area will be chosen randomly as control area and one area as the intervention.

Randomization (investigator's opinion)

Randomized

Randomization description

Two areas of each participant's burn site are randomly assigned as area one and area two. Since the study is double blind the physician chooses the burn areas by simple randomization. The creams of the intervention group and the control group are prepared by one of the project partners for each person and are given to the patient as one and two, to use cream one in area one and cream two in area two.

Blinding (investigator's opinion)

Double blinded

Blinding description

The coding is done by the project epidemiologist. The doctor receives the creams labeled with numbers 1 or 2, and by simple randomization, considers one area as area one, and prescribes cream number one, and considers the other area as area number 2 and prescribes cream number two. The doctor gives the patient additional information on how to use the creams. The patient also receives labeled creams that are similar in color and texture. The method of using both creams is the same, only for area one, cream number one and for area number 2, cream number 2 is used. The evaluator who evaluates the burn site at the beginning of the study and then at the end of the first, second, third and fourth weeks and collects the data also is not aware of coding system. The doctor, the evaluator and the patient are blind. The patient receives the coded drug (intervention or control). The data analyzer who drafts the article knows is aware of the coding.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine - Tehran University of Medical Sciences

Street address

Research ethics committees of school of medicine- Tehran university of medical sciences. Qods street, Keshavarz Blvd.

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Province

Tehran

Postal code

1417613151

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1510

Health conditions studied**1****Description of health condition studied**

Grade II burn wounds

ICD-10 code

T29.2

ICD-10 code description

Burns of multiple regions, no more than second-degree burns mentioned

Primary outcomes

1

Description

Wound size

Timepoint

At the beginning of the study (Before intervention), end of first week, end of second week, end of third week, end of fourth week.

Method of measurement

Photography and Image J software

2

Description

Epidermis Thickness

Timepoint

At the beginning of the study (Before intervention), end of first week, end of second week, end of third week, end of fourth week.

Method of measurement

Biometry

3

Description

Dermis Thickness

Timepoint

At the beginning of the study (Before intervention), end of the first week, end of the second week, end of the third week, end of the fourth week.

Method of measurement

Biometry

4

Description

wound healing velocity

Timepoint

At the beginning of the study (Before intervention), end of the first week, end of the second week, end of the third week, end of the fourth week.

Method of measurement

Photography and Image J software

Secondary outcomes

1

Description

Improving Life's Quality

Timepoint

At the beginning of the study and two week after finishing the study.

Method of measurement

Interviewing and giving out self assessment form

Intervention groups

1

Description

Intervention group: Silver Sulfadiazine 1% containing 0.001% Epidermal Growth Factor topical cream was used and the burn wound area is covered by sterile gauze, very 12 hours wound area is cleaned by normal saline and bandaged.

Category

Treatment - Drugs

2

Description

Control group: Silver Sulfadiazine 1% topical cream was used and the burn wound area is covered by sterile gauze, every 12 hours wound area is cleaned by normal saline and bandaged. In fact the control group receives the standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Hospital

Full name of responsible person

Majid Golkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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
Tehran University of Medical Sciences
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Borna Biopharma Science based Co.
Full name of responsible person
Samira Amiri
Street address
No. 1246, Tehran University Incubator of Pharmaceutical units , End of North Kargar St., Above Jalal Al-Ahmad, next to Tehran university dormitory, opposite of the Faculty of Physical Education, Tehran.
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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
Borna Biopharma Science based Co.
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
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Full name of responsible person
Majid Golkar
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Person responsible for updating data

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Privacy control

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study Protocol, clinical trial report, codes used in the analysis, study dictionary

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Public

Under which criteria data/document could be used

Sending an email to the person in charge of updating the results

From where data/document is obtainable

Sending an email to the person in charge of updating the results

What processes are involved for a request to access data/document

Receiving request email by the responsible person, assessing the request and sending the required data

Comments