

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### the efficacy of topical erythropoietin treatment on healing of second degree burned cutaneous burned wounds

#### Protocol summary

##### Study aim

Evaluation of the effect of topical erythropoietin in comparison with placebo on the healing of grade 2 burn wounds

##### Design

Erythropoietin and placebo creams will be made in the Pharmaceutics Laboratory of Yazd School of Pharmacy. Patients with second-degree burns referred to Yazd Martyrs Hospital in Yazd will be included in the study. Patients will receive erythropoietin or placebo creams once a day for two weeks. The steps will be covered by the patient, physician, and evaluators. In this way, the first executor of the sequence plan determines the allocation of people according to the order in which the sick people enter the study and puts the tablets in boxes of the same shape for the patient to consume, and identifies them with codes A or B.

##### Settings and conduct

Patients with second-degree burns referred to Yazd Martyrs Hospital in Yazd will be included in the study. Patients will receive erythropoietin or placebo creams once a day for two weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include referral to the burn center in the first 24 hours after the burn, having a second-degree and deep burn that covers less than 10% of the body surface, no concomitant disease that delays the healing process (such as diabetes, chronic kidney disease, malignancy, and chronic use of corticosteroids), lack of respiratory burns as well as burns with chemicals or electricity, lack of burns on the face, perineum, and hands.

##### Intervention groups

One group is the erythropoietin cream recipient, the other is the placebo cream recipient.

##### Main outcome variables

Comparison of wound healing percentage in two groups on days 1, 5, 9, 13

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190810044500N23**

Registration date: **2022-03-02, 1400/12/11**

Registration timing: **prospective**

Last update: **2022-03-02, 1400/12/11**

Update count: **0**

##### Registration date

2022-03-02, 1400/12/11

##### Registrant information

##### Name

Fatemeh Saghafi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 3419

##### Email address

f.saghafi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-08-23, 1401/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

the efficacy of topical erythropoietin treatment on healing of second degree burned cutaneous burned wounds

#### **Public title**

the efficacy of topical erythropoietin treatment on healing of second degree burned cutaneous burned wounds

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Presenting to the burn center in the first 24 hours after the burn Having grade II burns, superficial and deep, that involve less than 10% of the body's surface area No comorbidity that delays the repair process (such as diabetes, chronic kidney disease, malignancy, and chronic use of corticosteroids) Absence of respiratory burns as well as chemicals or electric burn No burns on the face and perineum and hand

##### **Exclusion criteria:**

Concurrent infection during the study Lack of response to treatment The need for skin graft surgery

#### **Age**

From **18 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Investigator

#### **Sample size**

Target sample size: **48**

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

Randomized

#### **Randomization description**

Patients were randomly assigned to two groups of 24 controls or interventions by the permutation block method. Twelve blocks of four are considered. Generation of random codes using Permuted Block Randomization method will be done with the help of Random allocation software (version 1). The first person who is eligible to enter the study is given number one and likewise, the last eligible person is given number 48. By using the software-generated table, patients receive each intervention A or B (Each of the letters A and B will be installed on similar containers of the interventions). In order to consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The steps will be covered from the perspective of the patient, the treating physician, and the assessors. The first presenter identifies the sequence of assignments of patients according to the order of entry of the patients into the study, and puts the erythropoietin and placebo

creams (identical from color, odor, and shape) into one-size boxes for patient use, and identifies them with A or B codes. The student then delivers the drugs to each individual patient

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Shahid Sadoughi University  
Medical Sciences

###### **Street address**

Shahid Sadoughi university of medical sciences,  
Professor Hesabi Blvd, Yazd, Iran.

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

8915173149

##### **Approval date**

2020-07-06, 1399/04/16

##### **Ethics committee reference number**

IR.SSU.MEDICINE.REC.1399.059

### **Health conditions studied**

#### **1**

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

Burn

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

L99

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

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

### **Primary outcomes**

#### **1**

##### **Description**

Mean time of wound healing

##### **Timepoint**

The wound healing process is measured during the study period on days 1, 3, 7, 10, 14, and 21 after starting to use Erythropoietin cream on the wound area

##### **Method of measurement**

Clinical examination

## 2

### **Description**

The rate of pigmentation

### **Timepoint**

The rate of pigmentation is measured during the study period on days 1, 3, 7, 10, 14, and 21 after starting to use Erythropoietin cream in the wound area.

### **Method of measurement**

Clinical examination

## 3

### **Description**

The rate of pain

### **Timepoint**

The rate of pain is measured during the study period on days 1, 3, 7, 10, 14, and 21 after starting to use Erythropoietin cream in the wound area

### **Method of measurement**

Clinical examination

## 4

### **Description**

The rate of pruritus

### **Timepoint**

The rate of pruritus is measured during the study period on days 1, 3, 7, 10, 14, and 21 after starting to use Erythropoietin cream in the wound area

### **Method of measurement**

Clinical examination

## **Secondary outcomes**

## 1

### **Description**

Complications observed

### **Timepoint**

End of the study

### **Method of measurement**

Based on the doctor's observation and the person's statements

## **Intervention groups**

## 1

### **Description**

Intervention group: Erythropoietin cream will be made in the Pharmaceutics Laboratory of Yazd School of Pharmacy. Patients with second-degree burns referred to Yazd Martyrs Hospital in Yazd will be included in the study. Patients will receive erythropoietin cream once a day for two weeks.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: Placebo cream will be made in the

Pharmaceutics Laboratory of Yazd School of Pharmacy. Patients with second-degree burns referred to Yazd Martyrs Hospital in Yazd will be included in the study. Patients will receive placebo cream once a day for two weeks.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

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

Emergency Department of Shohadaye Mehrab hospital, Yazd

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

Maryam Jafarpour Semiromy

#### **Street address**

Shohadaye Mehrab Hospital (Burn)., Hatamipour Alley., Shahid Sadoughi Burn Hospital Street., Pakenjad Blvd., Moalem Square

#### **City**

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#### **Province**

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#### **Postal code**

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#### **Phone**

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#### **Email**

Burn.hospital@chmail.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

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

Yazd University of Medical Sciences

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

Masoud Mirzaei

#### **Street address**

South Shahid Sadoughi Blvd., Bahonar Square

#### **City**

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#### **Province**

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#### **Phone**

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#### **Email**

Ravabet@ssu.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes  
**Title of funding source**  
Yazd 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**  
Yazd University of Medical Sciences  
**Full name of responsible person**  
Fateme Saghafi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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