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)

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+98 35 3820 3419

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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 Commitee of Shahid Sadoughi University Medical Sciencrs

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
Yazd
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Yazd
Postal code
8917615469
Phone
+98 35 3525 0093
Fax
+98 35 3525 6555
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
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3724 1171
Fax
+98 35 3724 0371
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

Fatemeh 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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Name of organization / entity

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Full name of responsible person

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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