

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Treatment of second-degree burn wound with PRP-Fibrin glue and repairing gel

Protocol summary

Study aim

Increasing the chance of healing second-degree burn wounds by increasing the effectiveness of PRP-FG in combination with the approved components in wound healing

Design

A clinical trial with the control group, factorial, Non-blind, Non-randomized, phase 2-3 on 40 patients.

Settings and conduct

First, the presence of second-degree burns and the conditions of using the treatment for the patient are confirmed by the specialist doctor at Imam Reza Hospital. After obtaining consent, the patient will be non-randomly and without blinding assigned to one of the 4 study groups (PRP-FG, Supraz, PRP-FG+Supraz, and Control). Interventions will be performed in the burn department of Imam Reza Hospital (Mashhad, Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having second-degree burns No smoking, alcohol, or drug addiction Not taking drugs that may interfere with wound healing Not having concurrent diseases that may cause problems in wound healing Informed consent of patients Exclusion criteria: The presence of a wound with an active infection or gangrene Failure to refer the patient for follow-up

Intervention groups

Group 1: PRP-FG is placed in the form of gel on the wound of 10 patients for 8 weeks. Group 2: approved compounds are placed in the form of gel on the wounds of 10 patients for 8 weeks. Group 3: The repairing gel used in the second group is placed on the wounds of 10 patients, and then platelet-rich fibrin is placed on it for 8 weeks. Group 4: For 10 patients with chronic wounds, only classical wound irrigation by normal saline (0.9%) will be continued for 8 weeks.

Main outcome variables

The size of the wound; Pain; and Time of the wound changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191228045924N6**

Registration date: **2023-11-12, 1402/08/21**

Registration timing: **prospective**

Last update: **2023-11-12, 1402/08/21**

Update count: **0**

Registration date

2023-11-12, 1402/08/21

Registrant information

Name

Daryoush Hamidi Alamdari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment of second-degree burn wound with PRP-Fibrin glue and repairing gel

Public title
Effect of PRP-Fibrin glue and Repairing gel in treatment of second-degree burn wounds

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of second-degree burns Having a body mass index of 18-35 No smoking, alcohol and drug addiction Not taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents Not having concurrent diseases that may cause problems in wound healing, such as cancers, vasculitis, kidney, liver, and heart failures Informed consent of patients
Exclusion criteria:
The presence of a wound with an active infection requiring intravenous antibiotics or gangrene requiring amputation Failure to refer the patient to the mentioned center for follow-up and dressing change on more than two occasions

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of Mashhad University of Medical Sciences

Street address

Daneshgah street, the central organization of University, Quraishi construction

City

Mashhad
Province
Razavi Khorasan
Postal code
9138813944

Approval date

2023-09-09, 1402/06/18

Ethics committee reference number

IR.MUMS.REC.1402.163

Health conditions studied

1

Description of health condition studied

Burn of second degree

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Change from Baseline Wound Size (length and width) will be assessed in digital images taken of the wound.

Timepoint

At the beginning of the study (0 days) and at the end of the eighth week of the intervention (8 weeks).

Method of measurement

digital images and ruler

2

Description

Visual Analog Scale changes for pain assessment

Timepoint

Every 48 hours for 8 weeks

Method of measurement

Pain will be evaluated by the visual analog scale system (VAS). The score is determined by measuring the distance (mm) between the no-pain anchor and the point that the patient marks, providing a range of scores from 0 - 10. A higher score indicates greater pain intensity.

3

Description

The duration of recovery is the number of days it will take for the wound to heal.

Timepoint

The interval from the beginning of the study (0 days) to wound healing

Method of measurement

Counting days

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: For 10 patients with second-degree burns, platelet-fibrin glue in the form of gel will be placed on the patient's wound. The number of times of use: use of fibrin gel is every 48 hours for 8 weeks, and this gel is used on the wound at the time of changing the dressing after irrigation of the wound. Fibrin glue is prepared in the clean room of the skin bank of Imam Reza Hospital. Fibrin glue is prepared in the clean room of the skin bank of Imam Reza Hospital from platelet and cryo samples taken from blood transfusion organization by project researchers and is not commercial.

Category

Treatment - Drugs

2

Description

Second intervention group: 10 patients with second-degree burns, the classical treatment for the wound will be performed, and the repairing gel with approved wound healing components in the form of gel will be used. The repairing gel will be manufactured by Omid Rajabi Pharmaceutical Factory, and the dosage of the components used is FDA-approved. The components are vitamin A (0.2 percent) - vitamin C (2 percent) - vitamin B3 (0.5 percent) - glycine amino acid. (0.5 percent) - ethanol (2 percent) - collagen (1 percent) - citric acid (2 percent) - glycerin (0.5 percent) - malic acid (1 percent) - urea (35 percent) - carboxymethyl cellulose (2 percent) - Sodium alginate (1 percent) - Benzoic acid (0.002 percent) - Propylene glycol (0.5 percent) - Methylene blue (0.1 percent) - Violet Dujancin (0.1%) - dimethyl sulfoxide (0.1%). The number of times of use: use of repairing gel is every 48 hours for 8 weeks, and these gels are used on the wound at the time of changing the dressing after irrigation of the wound.

Category

Treatment - Drugs

3

Description

Third intervention group: 10 patients with second-degree burns, in addition to the classical treatment, the repairing gel with approved wound healing components and platelet-fibrin glue will be placed on the wound. The repairing gel will be manufactured by Omid Rajabi Pharmaceutical Factory, and the dosage of the components used is FDA-approved. The components are vitamin A (0.2 percent) - vitamin C (2 percent) - vitamin B3 (0.5 percent) - glycine amino acid. (0.5 percent) - ethanol (2 percent) - collagen (1 percent) - citric acid (2 percent) - glycerin (0.5 percent) - malic acid (1 percent) - urea (35 percent) - carboxymethyl cellulose (2 percent) - Sodium alginate (1 percent) - Benzoic acid (0.002 percent) - Propylene glycol (0.5 percent) - Methylene blue (0.1 percent) - Violet Dujancin (0.1%) - dimethyl sulfoxide (0.1%). Fibrin glue is prepared in the clean

room of skin bank of Imam Reza Hospital. The number of times of use: use of repairing gel and fibrin gel is every 48 hours for 8 weeks, and these gels are used on the wound at the time of changing the dressing after irrigation of the wound.

Category

Treatment - Drugs

4

Description

Control group: 10 patients with second-degree burns, only the classical wound irrigation will be continued. The number of times of use: Every 48 hours for 8 weeks, the dressing is changed on the wound.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Daryoush Hamidi Alamdari

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Imam Reza Hospital, Daneshgah Ave

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Seyed Hasan Tavousi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

BURN

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available