

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effect of topical application of platelet-enriched fibrin glue with conventional dressing method on the second-degree burns wound healing

Protocol summary

Study aim

1) Comparison of the effect of local use of platelet-enriched throat fibrin with the usual dressing method on second degree burn wound healing according to age and gender 2) Comparison of the effect of the local use of platelet-enriched throat fibrin with the usual dressing method on the healing of 2nd degree burn wounds according to the type of burn. 3) Comparison of the effect of the local use of platelet-enriched throat fibrin with the usual dressing method on the healing of 2nd degree burn wounds in terms of burn percentage. 4) Comparison of the effect of local use of platelet-enriched throat fibrin with the usual dressing method on the healing of 2nd degree burn wounds according to the burn site. 5) Comparison of the effect of local use of platelet-enriched throat fibrin with the usual dressing method on second degree burn wound healing in terms of burn complications.

Design

A clinical trial with a control group and a parallel, one-sided blind, randomized with a table of random numbers will be conducted on 23 patients.

Settings and conduct

In the burn department of Imam Reza Hospital, Mashhad. Patients are unaware of the type of dressing, but the researcher is aware

Participants/Inclusion and exclusion criteria

Entry criteria: - 2nd degree burn confirmed by a doctor - Burn percentage between 5 and 20% - Willingness to participate in the study - Age between 18 and 60 years
Non-entry criteria: - Existence of a known systemic disease affecting wound healing, such as type 2 diabetes - Lack of consent to continue participating in the study - Skin sensitivities when using the dressing - Patients with underlying skin problems

Intervention groups

In the intervention group, platelet-enriched throat fibrin

dressing was used, and in the control group, the common dressing used in the burn department was used.

Main outcome variables

Speed up recovery time Scar reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220628055309N1**

Registration date: **2022-08-20, 1401/05/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-20, 1401/05/29**

Update count: **0**

Registration date

2022-08-20, 1401/05/29

Registrant information

Name

Mohammad amin Khojaste nezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3620 2366

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of topical application of platelet-enriched fibrin glue with conventional dressing method on the second-degree burns wound healing

Public title
Investigating the effect of platelet-enriched fibrin glue on second-degree burn wound healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

2nd degree burn certified by a doctor Burn percentage between 5 and 20 Trend to participate in the study Age between 18 and 60 years

Exclusion criteria:

Existence of systemic disease known to be effective on wound healing, such as type 2 diabetes Dissatisfaction to continue participating in the study Skin sensitivities while using the dressing Patients with chronic skin problems

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **23**

More than 1 sample in each individual

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

Each person must have two wounds of the second degree burn on the body at the same time, one of which will be dressed with a normal dressing and the other with a dressing impregnated with fibrin glue enriched with platelets.

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be conducted in two intervention and control groups in a one-sided blind way on patients with 2nd degree burns. So that each person must simultaneously have two separate 2nd degree burns on the body, which type of dressing to be done for that wound will be selected by a table of random numbers after the first wound is selected for dressing by the doctor. Obviously, the second wound on that person's body will be dressed with another type of dressing.

Blinding (investigator's opinion)

Single blinded

Blinding description

The dressings are pre-prepared and have the same appearance that the participant is unaware of the ingredients in them, but the researcher is.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Mashhad of Medical Sciences

Street address

No.11, Shahed 79/3,Shahed ave, Ghasem abad

City

Mashhad

Province

Razavi Khorasan

Postal code

9189985478

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.IAU.MSHD.REC.1401.008

Health conditions studied

1

Description of health condition studied

Superficial 2nd degree burn

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Wound healing rate: Patients will be examined by the attending physician in both groups for two weeks or until discharge or death at two-day intervals. So that the speed of wound healing in two groups will be compared on the fifth, seventh, ninth, eleventh and thirteenth days. The effectiveness of the dressings will be considered with the improvement of more than 90% of the wound, which will be determined by the opinion of the specialist doctor and the patient's therapist.

Timepoint

The speed of wound healing in two groups will be compared on the fifth, seventh, ninth, eleventh and thirteenth days.

Method of measurement

More than 90% healing of the wound, which is according

to the opinion of a specialist doctor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In people with superficial 2nd degree burns who have burns in two areas of the skin, in one of the areas of the burn, a dressing containing throat fibrin enriched with platelets is used. Then the patients will be examined in terms of the degree of healing by the attending physician for two weeks or until discharge or death at intervals of two days.

Category

Treatment - Surgery

2

Description

Control group: In patients with 2nd degree superficial burns who have burns in two areas of the skin, a normal dressing will be used in one of the burned areas. Normal dressing includes Vaseline gas with or without burn ointments according to the doctor's diagnosis and in the same way as it has been commonly used in the department. Then the patients will be examined by the attending physician for two weeks or until discharge or death at intervals of two days.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mohamad Amin Khojaste Nezhad

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No11, Shahed ave, Shahed 79/3, Ghasem Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

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

Mohamad Amin Khojaste Nezhad

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Latest degree

Bachelor

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

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