Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Increasing the effectiveness of platelet-fibrin glue in the healing of recalcitrant wounds by adding the repairing gel which has the approved components in wound healing

Protocol summary

Study aim
Comparison of the chance of healing chronic wounds with the synergistic treatment of healing gel and fibrin glue

Design
A clinical trial with the control group, factorial, triple-blind, randomized, phase 2-3 on 40 patients. Blocking will be used for randomization.

Settings and conduct
40 patients with chronic wounds, who did not respond to classical treatment after 3 months and the damage is still not healed, are included in the study. First group: 10 patients will be treated with platelet-fibrin glue in the form of a gel. Second group:10 patients will be treated with repairing gel. Third group:10 patients will be treated with repairing gel and platelet-fibrin glue. Fourth group: for 10 patients with chronic wounds, the classical wound irrigation will be continued. Place of study: Imam Reza Hospital - Surgery Department - Burns Department

Participants/Inclusion and exclusion criteria
Patients with a wound that has been at least 3 months old and has not been repaired by irrigation with normal saline and changing the dressing.

Intervention groups
First group: 10 patients with chronic wounds, the classical treatment will be performed, and then platelet-fibrin glue in the form of gel will be placed on the patient's wound. Second group: 10 patients with chronic wounds, 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. Third group:1 0 patients with chronic wounds, in addition to the classical treatment, the repairing gel with approved wound healing components and platelet-fibrin glue will be placed on the wound. Fourth group:10 patients with chronic wounds, only the classical wound irrigation will be continued.

Main outcome variables
wound area

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191228045924N5**
Registration date: **2023-07-10, 1402/04/19**
Registration timing: **prospective**

Last update: **2023-07-10, 1402/04/19**
Update count: **0**

Registration date
2023-07-10, 1402/04/19

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
2023-07-20, 1402/04/29

Expected recruitment end date
2024-01-19, 1402/10/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Increasing the effectiveness of platelet-fibrin glue in the healing of recalcitrant wounds by adding the repairing gel which has the approved components in wound healing

Public title

Investigating the effect of repairing gel and platelet-fibrin glue in the healing of wounds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a single wound on the body that has been at least 3 months old and has not been repaired by wound irrigation with normal saline and changing the dressing Having a body mass index of 18-35 Sign the informed consent by patient

Exclusion criteria:

Having concurrent diseases that may cause problems in wound healing, such as cancers, vasculitis, kidney and liver failure, and heart failure Taking certain drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The blocked method is used to avoid significant imbalances in the number of participants assigned to each group. Block randomization ensures that there is no significant imbalance between groups at any time during randomization, and at certain points the number of participants in each group is equal. Random number table using www.randomization.com In the random block method, 10 blocks of four of different permutations of letters ABCD are considered, and patients are divided into four groups accordingly. Randomization Type: Blocked Allocation Concealment method The sealed envelope is used as a means of randomization and concealment. The method of sealed envelopes is that the envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randomaize.com and placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. First, the purpose of the study is explained to the person who meets the stated conditions, and if the person wishes, he signs the informed consent form and takes an envelope, and then opens it based on the contents of the envelope, the person is in group 1 or 2 or 3 or 4 is entered.

Blinding (investigator's opinion)

Triple blinded

Blinding description

First, this study is explained to the participants it is a three-blind study and includes three intervention groups and one control group. 40 patients with chronic wounds, who did not respond to classical treatment after 3 months and the damage is still not healed, are included in the study. 10 patients in each group: Group 1 (fibrin glue) - Group 2 (repairing gel) - Group 3: (platelets-fibrin glue and repairing gel) - Group 4: (classic wound irrigation treatment). The participants will not know which group they belong to. The statistical analyzer and evaluator are not also informed about the groups.

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 Building

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Razavi Khorasan

Postal code

9138813944

Approval date

2023-06-17, 1402/03/27

Ethics committee reference number

IR.MUMS.REC.1402.089

Health conditions studied

1

Description of health condition studied

Chronic Wound

ICD-10 code

T01.9

ICD-10 code description

Multiple open wounds, unspecified

Primary outcomes

1

Description
The amount of pain
Timepoint
It is measured after two days of changing the dressing.
Method of measurement
Visual Analogue Scale

2

Description
The duration of recovery, which is the number of days it takes for the wound to heal.
Timepoint
Every 24 hours (every day)
Method of measurement
By visual observation

3

Description
Presence of inflammation and infection
Timepoint
Before the intervention and after the intervention every week for two month
Method of measurement
Clinical examination

4

Description
Quality of Life
Timepoint
Before the intervention and after the intervention
Method of measurement
Completing the SF36 questionnaire

Secondary outcomes

1

Description
Reepithelialisation and wound closure
Timepoint
Every week for two month after dressing
Method of measurement
Clinical observation

Intervention groups

1

Description
First intervention group: 10 patients with chronic wounds, the classical treatment will be performed, and then platelet-fibrin glue in the form of gel will be placed on the patient's wound. 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. Fibrin glue is prepared in the clean room of skin bank of Imam Reza Hospital.
Category
Treatment - Drugs

2

Description
Second intervention group: 10 patients with chronic wounds, 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%), which is prepared as a gel. 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

3

Description
Third intervention group:10 patients with chronic wounds, 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%), which is prepared as a gel. 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 chronic wounds, 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Daryoush Hamidi Alamdari

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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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
Yes - There is 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

Title and more details about the data/document
All data related to the project after the unidentifiable people will be shared.

When the data will become available and for how long
After the completion of the study and data analysis, approximately 5 months after the completion of the interventions

To whom data/document is available
Researchers working in academic and scientific institutions and physicians

Under which criteria data/document could be used
According to the policies of the journal in which the article will be published, the data will be made available.

From where data/document is obtainable
the corresponding author of the article

What processes are involved for a request to access data/document
n The request should be sent by email to the corresponding author and he will respond as soon as possible after reviewing the request.

Comments