Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the safety and efficacy of gelatin-chitosan hydrogel-based wound dressing in second degree B burn repair: a clinical trial

Protocol summary

Study aim
Investigation of the safety and efficacy of gelatin-chitosan hydrogel-based wound dressing in second degree B burn repair: a clinical trial

Design
Clinical trial with a control group and an intervention group, with parallel groups, single-blind, randomized according to a random number table, phase 1 on 10 burn patients

Settings and conduct
The intervention site is Motahari Burn Hospital and Skin and Stem Cell Research Center. Blinding was performed in this study and the data analyst was unaware of the type and structure of the dressing in question.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with second-degree B burns, age 18 to 45 years, limited areas of involvement.
Exclusion criteria: Patients with chronic inflammatory underlying diseases, patients with immune system disorders

Intervention groups
In the intervention group, patients will receive wound dressings every other day, and in the control group, patients will receive standard treatment.

Main outcome variables
The amount of granulation tissue, the duration of wound healing, the size of the wound surface

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200127046282N56**
Registration date: **2025-11-12, 1404/08/21**
Registration timing: **prospective**

Last update: **2025-11-12, 1404/08/21**
Update count: **0**

Registration date
2025-11-12, 1404/08/21

Registrant information

Name
Sona Zare

Name of organization / entity
Skin and Stem Cell Research Center, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2665 7438

Email address
sonazarebio@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-21, 1404/08/30

Expected recruitment end date
2026-01-20, 1404/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the safety and efficacy of gelatin-chitosan hydrogel-based wound dressing in second degree B burn repair: a clinical trial

Public title
Studying the effect of gelatin-chitosan hydrogel-based wound dressing on burn healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with second-degree burns B Age 18 to 45 years Limited affected areas

Exclusion criteria:

Patients with chronic inflammatory diseases Patients with impaired immune system

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

1

Groups that have been masked

- Data analyser

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are divided into two groups based on a simple randomization method using a random number table. In this method, a set of numbers without a pattern is randomly generated and tabulated. Each of the 10 study patients has a random number.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyst does not know how the study was grouped.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Working Group/Committee, Faculty of Medicine - Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd

City

Tehran

Province

Tehran

Postal code

1937957511

Approval date

2025-07-14, 1404/04/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1404.249

Health conditions studied

1

Description of health condition studied

Burn and wound

ICD-10 code

T23.2

ICD-10 code description

Burn of second degree of wrist and hand

Primary outcomes

1

Description

The size of the granulation tissue formed in the wound

Timepoint

Before the intervention and six days after the last intervention

Method of measurement

Wound imaging and analysis using Image J 1.52v software (scientific image processing and analysis software)

2

Description

Wound surface and depth

Timepoint

Before the intervention and six days after the last intervention

Method of measurement

Software Image J

Secondary outcomes

1

Description

Pain from burn wounds

Timepoint

Six days after the first intervention

Method of measurement

In the form of questions and answers from the patient

Intervention groups

1

Description

Intervention group: In the intervention group, patients will receive wound dressings every other day.

Category

Treatment - Other

2

Description

Control group: patients will receive standard treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Nilforoushzadeh

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No 4, Maryam Alley, South Kamraniyeh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

Street address
Vice President for Research and Technology, 6th Floor, Central University Organization, corner of Qods Street, Keshavarz Boulevard

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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
Tehran 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
Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person
Sona Zare

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Cellular and Molecular biology

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Person responsible for scientific inquiries

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Sharif University of Technology

Full name of responsible person
Amir Shamloo

Position
Professor

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Other areas of specialty/work
Tissue Engineering

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Person responsible for updating data

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researcher

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Cellular and Molecular Biology

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable