

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Fabrication and evaluation of the effectiveness of the new generation of wound dressings based on Gelatin/Chitosan hydrogel containing nanoparticles and mesenchymal stem cells derived condition medium to accelerate the healing of wounds (phase 1 & II clinical trial)

Protocol summary

Study aim

Fabrication and evaluation of the effectiveness of the new generation of wound dressings based on Gelatin/Chitosan hydrogel containing nanoparticles and mesenchymal stem cells derived condition medium to accelerate the healing of wounds (phase 1 & II clinical trial)

Design

Clinical trial with two control groups and one intervention group, with parallel groups, double-blind, randomized based on random number table, phase 1-2 on 30 burn patients

Settings and conduct

The intervention site is Motahari Burn Hospital and Skin and Stem Cell Research Center. In this study, a course was performed and not all patients, including the patient and the data analyzer, were aware of the type and structure of the dressing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18-50 years old with grade 2 burns. Exclusion criteria: Patients with chronic inflammatory diseases and immune disorders

Intervention groups

The study groups will include 10 people receiving medium conditioned wounds, 10 people receiving medium conditioned wounds and 10 people receiving 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: **IRCT20200127046282N17**

Registration date: **2022-06-02, 1401/03/12**

Registration timing: **prospective**

Last update: **2022-06-02, 1401/03/12**

Update count: **0**

Registration date

2022-06-02, 1401/03/12

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

2022-06-22, 1401/04/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fabrication and evaluation of the effectiveness of the new generation of wound dressings based on Gelatin/Chitosan hydrogel containing nanoparticles and mesenchymal stem cells derived condition medium to accelerate the healing of wounds (phase 1 & II clinical trial)

Public title
Evaluation of the effectiveness of wound dressing based on gelatin/chitosan hydrogel to accelerate wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18-50 years Patients with grade 2 burns
Exclusion criteria:
Patients with chronic inflammatory diseases Patients with impaired immune system

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are divided into three groups based on a simple randomization method using a random number table. In this method, a set of non-patterned numbers is randomly generated and converted into a table. Each of the 30 patients in the study has a random number. The number of each person in measure 3 is equal to zero, one or two. Module zero will be the intervention group, module one and two of each control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
30 patients are divided into three groups of 10 to study. The study groups will include 10 people receiving medium conditioned wounds, 10 people receiving medium conditioned wounds and 10 people receiving standard treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Keshavarz blvd
City
Tehran
Province
Tehran
Postal code
1937957511
Approval date
2022-05-11, 1401/02/21
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.146

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

Control group: Ten people will receive standard treatment.

Category

Treatment - Other

2

Description

Control group: Ten people will receive non-conditioned wound dressings.

Category

Treatment - Other

3

Description

Intervention group: Ten people will receive medium-conditioned wounds.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No 4, Maryam Alley, South Kamraniyeh Street,
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2

Recruitment center

Name of recruitment center

Shahid Motahari Educational and Medical Center

Full name of responsible person

Mostafa Dahmardehei

Street address

Shahid Motahhari Burn Hospital, Rashid-Yasemi Ave,

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m.dahmardehei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin and Stem cell Research Center of Tehran
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Full name of responsible person

Mohammad Ali Nilforoushzadeh

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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

Skin and Stem cell Research Center of 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

Tehran University of Medical Sciences

Full name of responsible person

Jafar Ai

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue engineering

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mostafa Dahmardehei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Plastic & Reconstructive Surgery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

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