# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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
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No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran
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### 2

**Recruitment center**
**Name of recruitment center**
Shahid Motahari Educational and Medical Center
**Full name of responsible person**
Mostafa Dahmardehei
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Shahid Motahhari Burn Hospital, Rashid-Yasemi Ave, Valieasr Ave, Tehran, Iran.
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## Sponsors / Funding sources

### 1

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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**
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**Position**
Professor
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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**
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