Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of electrospun nanofibrous wound dressing on superficial second-degree burn wounds (clinical trial phase I)

Protocol summary

Study aim
Preparation and fabrication of nanofibrous wound dressings based on polycaprolactone, gelatin, and methacrylated copolymer and clinical evaluation of nanofibrous wound dressings on superficial second-degree burn wounds

Design
The clinical trial has three intervention groups and one control group, double-blind, randomized, phase 1 on 45 second-degree burn patients.

Settings and conduct
Initially, three groups of nanofibrous wound dressings, including polycaprolactone/gelatin wound dressing, polycaprolactone/methacrylated copolymer wound dressing, and methacrylated copolymer wound dressing, were prepared using the electrospinning method. Patients who met the inclusion criteria were enrolled in the study. Sterility, washing, and disinfection of the burn site were performed uniformly for all patients across the entire wound surface according to hospital protocols. The wound area was then divided into two parts, and the type of dressing was randomly assigned to each site with the patient's awareness. A nanofibrous wound dressing was applied to area A, while a Mepilex foam dressing (control sample) was applied to area B. Finally, the evaluation was carried out on superficial second-degree burn wounds, and the variables were studied. Patient recruitment and the study were conducted in two centers: Shahid Motahari Hospital in Tehran and Kawsar Hospital in Sanandaj.

Participants/Inclusion and exclusion criteria
superficial second-degree burn wound

Intervention groups
Polycaprolactone/Gelatin Wound Dressing
Polycaprolactone/Methacrylated Copolymer Wound Dressing
Methacrylated Copolymer Wound Dressing
Mepilex foam wound dressing

Main outcome variables
Re-epithelialization rate; wound healing time; wound healing quality; dressing changes during the treatment period; comfort; pain; dressing adhesion; erythema; edema

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250408065259N1**
Registration date: **2025-12-21, 1404/09/30**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-21, 1404/09/30**
Update count: **0**

Registration date
2025-12-21, 1404/09/30

Registrant information

Name
Mohamad Pezeshki-Modaress

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-12, 1403/05/22

Expected recruitment end date
2026-02-21, 1404/12/02

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of electrospun nanofibrous wound dressing on superficial second-degree burn wounds (clinical trial phase I)

Public title

Evaluation of electrospun wound dressing on burn wound

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18–70 years Both sexes Superficial second-degree burn wounds No prior burns at the current site No acute psychiatric disorders No comorbidities No immunosuppressive therapy No massive unstable trauma Completion of informed consent form

Exclusion criteria:

First and third degree burn wounds burns on joints, face, perineum Pregnancy or breastfeeding Patients with diabetic and infected wounds Presence of a chronic skin disease

Age

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

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **45**

More than 1 sample in each individual

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

Each participant receives a coded study sample and a conventional control sample simultaneously.

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and the surgeon The samples are coded by the project executor in similar packaging and provided to the surgeon. Therefore, neither the patient nor the doctor is aware of the type of wound dressings, and the reports are completed only with the assigned codes

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of Iran University of Medical Sciences

Street address

Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences, Central Headquarters Building, Vice President for Research and Technology

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2024-01-17, 1402/10/27

Ethics committee reference number

IR.IUMS.REC.1402.938

Health conditions studied

1

Description of health condition studied

superficial second-degree burn wounds

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

Re-epithelialization

Timepoint

Day 0, 4, 9, and 14

Method of measurement

Photography using Image J software

2

Description

Wound healing quality

Timepoint

Day 0, 4, 9, and 14

Method of measurement

Surgeon evaluation through scoring poor, moderate, good, and excellent

3

Description

Wound dressing change

Timepoint

During the treatment period

Method of measurement

Surgeon's evaluation

4

Description
Patient comfort level
Timepoint
End of study
Method of measurement
By the patient through scoring of dissatisfaction, moderate, good and excellent

5

Description
Pain
Timepoint
Day 0, 4, 9, and 14
Method of measurement
Visual Analogue Scale

6

Description
Wound dressing adhesion
Timepoint
End of study
Method of measurement
Surgeon's evaluation through scoring of dissatisfaction, moderate, good and excellent

7

Description
Erythema
Timepoint
End of study
Method of measurement
Surgeon's evaluation through scoring of Very low, low, moderate and severe

8

Description
Edema
Timepoint
End of study
Method of measurement
Surgeon's evaluation through scoring of without edema, low, moderate and severe

Secondary outcomes

empty

Intervention groups

1

Description
This intervention includes patients with superficial second-degree burn wounds who receive a polycaprolactone/gelatin electrospun nanofibrous dressing with an area of 100 cm2 (10 cm x 10 cm). An explanation of the objectives of the study and the type of dressing used is given to the patient and a written consent is obtained from him/her. The number of patients is 10 to 15. First, the sterility conditions, washing and disinfection of the burn site are performed similarly in all patients according to hospital protocols across the entire wound surface. Then the wound area is divided into two parts (for dressing and control), and the type of dressing is assigned to the wound site randomly. After implementing the above protocol, the aforementioned nanofibrous dressing is placed on the wound and studied over a 14-day period on days 0, 4, 9 and 14. It should be noted that the dressing was fabricated by the research team and is simply a nanofibrous dressing without a drug component.
Category
Treatment - Devices

2

Description
This intervention includes patients with superficial second-degree burn wounds who receive a polycaprolactone/methacrylate copolymer electrospun nanofibrous dressing with an area of 100 cm2 (10 cm x 10 cm). An explanation of the objectives of the study and the type of dressing used is given to the patient and a written consent is obtained from him/her. The number of patients is 10 to 15. First, the sterility conditions, washing and disinfection of the burn site are performed similarly in all patients according to hospital protocols across the entire wound surface. Then the wound area is divided into two parts (for dressing and control), and the type of dressing is assigned to the wound site randomly. After implementing the above protocol, the aforementioned nanofibrous dressing is placed on the wound and studied over a 14-day period on days 0, 4, 9 and 14. It should be noted that the dressing was fabricated by the research team and is simply a nanofibrous dressing without a drug component.
Category
Treatment - Devices

3

Description
This intervention includes patients with superficial second-degree burn wounds who receive a methacrylate copolymer electrospun nanofibrous dressing with an area of 100 cm2 (10 cm x 10 cm). An explanation of the objectives of the study and the type of dressing used is given to the patient and a written consent is obtained from him/her. The number of patients is 10 to 15. First, the sterility conditions, washing and disinfection of the burn site are performed similarly in all patients according to hospital protocols across the entire wound surface. Then the wound area is divided into two parts (for dressing and control), and the type of dressing is assigned to the wound site randomly. After implementing the above protocol, the aforementioned nanofibrous dressing is placed on the wound and studied over a 14-day period on days 0, 4, 9 and 14. It should be noted that

the dressing was fabricated by the research team and is simply a nanofibrous dressing without a drug component.

Category

Treatment - Devices

4

Description

The control group also includes patients with superficial second-degree burns who receive a commercial polyurethane-based foam dressing, Mepilex , from Monlike, Sweden, as a wound covering bed without a drug component, with an area of 100 square centimeters (10 cm x 10 cm). The objectives of the study and the type of dressings used are explained to the patient and a written consent is obtained from him/her. The number of patients is 10 to 15. First, the sterility conditions, washing and disinfection of the burn site are performed similarly in all patients according to hospital protocols over the entire wound surface. Then, the wound area is divided into two parts (for dressing and control), and the type of dressing is assigned to the wound site randomly. After implementing the above protocol, the commercial dressing is placed on the wound and studied over a period of 14 days on days 0, 4, 9 and 14.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Motahhari Hospital
Full name of responsible person
Dr Tayyeb Ghadimi
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Shahid Motahari Hospital, Rashid Yasemi Street, Vanak Square
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hospital.motahari@iums.ac.ir

2

Recruitment center

Name of recruitment center
Kawsar Hospital
Full name of responsible person
Dr Farhang Safarnejad
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Burhanuddin Hamdi Blvd, Pasdaran Blvd
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mohamad Pezeshki Modaress
Position
Associate Professor
Latest degree
Ph.D.

Other areas of specialty/work
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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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Questionnaires, study protocol; statistical analysis; consent forms, clinical study report; codes used in analysis; data classification system
When the data will become available and for how long
The access period begins 12 months after the results are published.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
It is possible to use data/documents for research purposes.
From where data/document is obtainable
Burn Research Center, Iran University of Medical Sciences Address: Burn Research Center, Shahid Motahari Hospital, Rashid Yasemi Street, Valiasr Street postal Code: 1996714353 Contact Number: 02188884275 email: burncenter.iran@gmail.com
What processes are involved for a request to access data/document
One month after receiving the email and confirming the application details
Comments