

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the safety and effectiveness of smart biodegradable nanofiber dressing in the treatment of deep 2nd degree burn wounds (first and second phase of clinical trial)

Protocol summary

Study aim

Investigating the safety and effectiveness of smart biodegradable nanofiber dressing in the treatment of deep 2nd degree burn wounds (first and second phase of clinical trial)

Design

Randomized clinical trial phase 2, with a control group, with blinding, will be conducted on 16 patients and 32 volunteer wound sites.

Settings and conduct

The study will be performed in Velayat Hospital in Rasht and Mousavi hospital in Zanjan. 16 Men or women with second-degree Burning areas between 20-50% will be selected and enrolled in the study after signing a consent form. Wounds are first washed with normal saline, Then, according to groups type (intervention or control) a polymer dressing containing lactic acid and s-caprolactone or Suprathel wound dressing is placed on the wound sites and bandaged with sterile gauze. Before intervention and at the end of 1, 3 and, 7,14 and 28 days changes in burning parameters will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range from 18 to 65 years, acute burn in less than 24 hours, burn level of 20 to 50%, filling in the informed consent form, at least 2 recorded records of the variables of hospitalization in patients. exclusion criteria: pregnant women, underlying diseases.

Intervention groups

In the control group, a part of the patient's burn wound will be randomly selected and will receive the suprathel dressing, and in the intervention group, a part of the patient's burn wound will be randomly selected and will receive a polymer dressing containing lactic acid and s-caprolactone.

Main outcome variables

Local outcomes, systemic outcomes, duration of hospitalization, wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231122060138N1**

Registration date: **2023-12-03, 1402/09/12**

Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**

Update count: **0**

Registration date

2023-12-03, 1402/09/12

Registrant information

Name

Ahmadreza Mobayen

Name of organization / entity

Country

Iran (Islamic Republic of)

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mobaien1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-12-10, 1403/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the safety and effectiveness of smart biodegradable nanofiber dressing in the treatment of deep 2nd degree burn wounds (first and second phase of clinical trial)

Public title

Investigating effectiveness of smart biodegradable nanofiber dressing in the treatment of 2nd degree burn wounds

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patient between 18 and 65 years old Refer to the treatment center in less than 24 hours Burn percentage ranges from 20-50% Fill out the informed consent form There should be at least 2 recorded records of the investigated variables. Patients should stay in the hospital for at least three days

Exclusion criteria:

Having severe hypertension BP $\geq$ 160/90 mmHg High cardiac troponin pregnant women Immune system defect Anticoagulation problems, bleeding disorders, or heart disease

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **16**

More than 1 sample in each individual

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

In this research, according to the implementation method, a part of the burn wound of selected patients receives the original Supratel dressing and is considered as the control group, and another part of the patient's wound is randomly selected as the intervention group . They will receive lactic acid and s-caprolactone wound dressing.

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, in order to assign patients to the intervention and control groups, the restricted randomization approach will be used in parallel with the Random Allocation Rule method. In the random assignment process, the person who creates the random sequence is the analyst in this study. Also, the person who registers the participants based on the entry and exit criteria in the study will be one of the clinic nurses, and the person who allocates the participants in the intervention and control groups will be the project manager.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind the researcher and the patient, dressings that are similar in color and shape are used in the control and intervention areas. The analyzer is blinded based on the coding of the dressings.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Zanjan University of Medical Sciences

Street address

The ethics committee of Zanjan University of Medical Sciences, first floor, Northside of Azadi Boulevard, Zanjan.

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Zanjan

Province

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4525613113

Approval date

2023-10-31, 1402/08/09

Ethics committee reference number

IR.ZUMS.REC.1402.192

Health conditions studied**1****Description of health condition studied**

Second degree burn

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head, face, and neck

Primary outcomes**1****Description**

Local outcomes

Timepoint

At the beginning of the study (before the intervention) and 1, 3, 7, 14 and 28 days after applying the wound dressing

Method of measurement

Clinical observations and filling the checklist in 6 time

points

2

Description

systemic outcomes

Timepoint

At the beginning of the study (before the intervention) and 1, 3, 7, 14 and 28 days after applying the wound dressing

Method of measurement

Clinical observations and filling the checklist in 6 time points

Secondary outcomes

1

Description

Wound healing rate

Timepoint

At the beginning of the study (before the intervention) and 1, 3, 7, 14, and 28 days after applying the wound dressing

Method of measurement

Based on examination done by evaluators

Intervention groups

1

Description

Intervention group: Randomly, the site of the intervention group will be selected and will receive polymer dressing containing lactic acid and s-caprolactone.

Category

Treatment - Other

2

Description

Control group: A part of the burn wound of the patients is randomly selected and receives the original Suprathel dressing

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان ولایت

Full name of responsible person

دکتر محمدرضا مبین

Street address

3 floor, Burn and Regenerative Medicine Research Center, Velayat hospital, Namjo street, Rasht, Guilan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Ahmadreza Mobayen

Position

Tropical and Infectious Diseases Specialist

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

-

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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