

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of bacterial nanocellulose wound dressings and standard treatment in the healing of second degree burn wounds: a randomized controlled clinical trial

Protocol summary

Study aim

Comparison of the use of nanocellulose dressing with the standard method of burn treatment in the recovery of patients with 2nd degree burns.

Design

Controlled clinical trial with parallel groups, without blinding, randomized, phase 3 on 24 patients. Lottery of sealed envelopes will be used for randomization.

Settings and conduct

This trial will be conducted as a single center in the Shahid Madani accident center of Karaj. The number of 24 patients who meet the necessary conditions to participate in the study will be included in the study and randomly and by lottery will be placed in one of the groups of standard treatment or treatment with nanocellulose dressing. Duration of hospitalization, wound healing time, wound infection, hypertrophic scar and patient satisfaction with the treatment will be measured. The level of pain and itching of the patient on the first to third day will also be checked using VAS and finally all these items will be compared between the study groups.

Participants/Inclusion and exclusion criteria

Having second-degree burns in the limbs or trunk (with TBSA below 10%), being 18 and 75 years old, as well as not having chronic heart, vascular, liver and kidney diseases, not being pregnant, absence of infection in the burn wound and not being under treatment with systemic cortisone

Intervention groups

The nanocellulose coating is placed on the wound and covered with a sterile gauze. In this group, the dressing will be changed every three days without removing the nanocellulose dressing.

Main outcome variables

Duration of hospitalization, wound healing time, wound infection, hypertrophic scar and patient satisfaction, the

level of pain and itching of the patient on the first to third day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160117026069N6**

Registration date: **2023-01-26, 1401/11/06**

Registration timing: **prospective**

Last update: **2023-01-26, 1401/11/06**

Update count: **0**

Registration date

2023-01-26, 1401/11/06

Registrant information

Name

Fereshteh Ansari

Name of organization / entity

Razi Vaccine and Serum Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 26 3405 0400

Email address

ansarif@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of bacterial nanocellulose wound dressings and standard treatment in the healing of second degree burn wounds: a randomized controlled clinical trial

Public title

Bacterial nanocellulose wound dressings for the healing of second degree burn wounds

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having second degree burns on the limbs or trunk (with TBSA below 10%)

Exclusion criteria:

Pregnancy Chronic heart, kidney and liver diseases
Wound infection Systematic cortisone use

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Sealed envelopes are considered as the number of patients, whose content determines which group each person belongs to. One of these envelopes is selected for each patient by lottery, and then this envelope is opened and the allocation of the patient will be determined after opening the envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Alborz University of Medical Sciences

Street address

Saffarian Alley, Golshahr Blvd, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.ABZUMS.REC.1401.283

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

Second degree burn ulcer

ICD-10 code

M61.3

ICD-10 code description

Calcification and ossification of muscles associated with burns

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

Duration of hospitalization

Timepoint

When the patient discharged from the hospital

Method of measurement

Information recorded in the patient file

2**Description**

Duration of recovery

Timepoint

Daily until hospitalization and weekly visits thereafter

Method of measurement

Observation of the physician

Secondary outcomes**1****Description**

Wound infection

Timepoint

Daily during hospitalization and weekly visits thereafter

Method of measurement

Observation of the physician

2**Description**

Hypertrophic scar

Timepoint

The last visit

Method of measurement

Observation of the physician

3**Description**

Patient satisfaction

Timepoint

The last visit

Method of measurement

Questioning the patient in the form of yes or no

4**Description**

Pain

Timepoint

First day, second day, third day

Method of measurement

Asking the patient based on the VAS scale

5**Description**

Itching

Timepoint

First day, second day, third day

Method of measurement

Asking the patient based on the VAS scale

Intervention groups**1****Description**

Intervention group: After preliminary and necessary measures such as washing and disinfecting the wound, nanocellulose coating is placed on the wound and covered with a sterile gauze. In this group, the dressing will be changed every three days without removing the nanocellulose dressing.

Category

Treatment - Other

2**Description**

Control group: After preliminary and necessary measures such as washing and disinfecting the wound, the dressing is done using usual ointments (usual treatment) and the whole dressing is changed once every three to five days.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Madani medical education and treatment

center

Full name of responsible person

Leila Hajimaghsoudi

Street address

Shahid Madani medical education and treatment center, Shahid Madani Sq., Shahid Madani Blvd., Talegani Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

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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

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Hadi Pourjafar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Food safety and Health

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Fereshteh Ansari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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

Razi Vaccine and Serum Research Institute

Full name of responsible person**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

Not applicable

Title and more details about the data/document

All of the participants' individual data

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

All researchers working in academic and scientific
institutions and people working in the industry

Under which criteria data/document could be used

If a request with this theme is received, a decision will be
made with the opinion of the research team.

From where data/document is obtainable

To the project manager, Dr. Hadi Pourjafar

What processes are involved for a request to access data/document

After submitting the request to the project manager, this
request will be reviewed by a committee with the
presence of all the people involved in the project, and
then if the committee gives a positive answer, the data
will be provided to the applicant.

Comments