Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of nanocellulose wound dressing with standard treatment in diabetic foot ulcer healing: a randomized controlled clinical trial

Protocol summary

Study aim
Investigating the benefits of using bacterial nanocellulose dressing in the healing of diabetic foot ulcers.

Design
Controlled clinical trial with parallel groups, without blinding, randomized, phase 3 on 36 patients. Lottery of sealed envelopes will be used for randomization.

Settings and conduct
This trial will be conducted in a single center and in Imam Ali Karaj Hospital. The number of 36 patients who meet the necessary criteria to 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. The time to full healing, the average percentage of wound healing will be measured in weekly visits and patient satisfaction at the end of the treatment. Finally, all these cases will be compared between the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criterion is a non-infectious lower extremity wound with an ABI (ankle/brachial index) of four or more. Patients with osteomyelitis, heart failure, patients undergoing chemotherapy, dialysis and Wagner grade IV or V will be excluded.

Intervention groups
The intervention group includes patients with diabetic foot ulcers who receive standard treatment intervention with the use of bacterial nanocellulose coating. The control group includes patients with diabetic foot ulcers who receive only the standard treatment.

Main outcome variables
Time to full healing, average percentage of wound healing in weekly visits and patient satisfaction

General information

Reason for update
Considering that BNC dressing was used for infected wounds in several cases and the results were satisfactory, we decided to include people with infected diabetic foot ulcers in the study.

Acronym

IRCT registration information
IRCT registration number: **IRCT20160117026069N7**
Registration date: **2023-02-11, 1401/11/22**
Registration timing: **prospective**

Last update: **2024-05-13, 1403/02/24**
Update count: **1**

Registration date
2023-02-11, 1401/11/22

Registrant information

Name
Fereshteh Ansari

Name of organization / entity
Razi Vaccine and Serum Research Institute

Country
Iran (Islamic Republic of)

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+98 26 3405 0400

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ansarif@ut.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-11-22, 1402/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of nanocellulose wound dressing with standard treatment in diabetic foot ulcer healing: a randomized controlled clinical trial

Public title
Nanocellulose dressing for diabetic foot ulcer healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A lower limb ulcer with an ABI (ankle/brachial index) of four or more
Exclusion criteria:
Osteomyelitis Heart failure Patients undergoing chemotherapy Patients undergoing dialysis Wagner grade IV or V
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
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
2023-01-22, 1401/11/02
Ethics committee reference number
IR.ABZUMS.REC.1401.282

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer
ICD-10 code
Z86.31
ICD-10 code description
Personal history of diabetic foot ulcer

Primary outcomes

1

Description
Time to full healing
Timepoint
The last weekly visit of the patient
Method of measurement
The examination of the physician

2

Description
Average percentage of wound healing (relative to initial wound size) in weekly visits
Timepoint
Weekly to the end of the treatment
Method of measurement
Comparison of the size of the wound with the initial size by photographing next to the ruler

3

Description
Patient satisfaction
Timepoint
The last visit of the patient
Method of measurement
Asking from the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The standard treatment method includes debridement, removing pressure from the leg with plaster or other tools, or using a dry pressure

bandage, which will be done in this group. If necessary, debridement will be done with sharp surgical instruments and then the wound area will be washed with physiological serum. In this group, the nanocellulose coating made by the research team will be selected with the appropriate size of the wound, and the wrinkles on its surface will be smoothed using moist gauze with saline. According to the available evidence, a single nanocellulose coating is sufficient for complete wound healing, but this coating will be replaced if needed. Wound decompression devices or dry pressure bandages will also be applied weekly to all wounds.

Category

Treatment - Other

2

Description

Control group: The standard treatment method includes debridement, removing pressure from the leg with plaster or other tools, or using a dry pressure bandage, which will be done in this group. If necessary, debridement will be done with sharp surgical instruments and then the wound area will be washed with physiological serum. In this group, in every visit, the wound will be washed and bandaged using the usual dressing. Wound decompression devices or dry pressure bandages will be applied weekly to all wounds.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam ali medical eduction and treatment center

Full name of responsible person

Reyhaneh Mahmoodian

Street address

Imam Ali Medical Education and Treatment Center, Vali-asr Blvd., Esteghlal Blvd., Esteghlal Sq.

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3154686695

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reyhanehmahmoodian@gmail.com

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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Vice-Chancellor for Research and Technology, Gulshahr, Safarian Alley

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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

Street address

Vice-Chancellor for Research and Technology, Gulshahr, Safarian Alley

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Reyhaneh Mahmoodian

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Endocrinology and Metabolism

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Person responsible for updating data

Contact

Name of organization / entity
Razi Vaccine and Serum Research Institute

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Fereshteh Ansari

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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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
All non-identifiable personal data of participants, study protocol, statistical analysis map, informed consent form, clinical study report, codes used in analysis, and data dictionary will be shared after the end of the study.

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
The data can be analyzed and used within the framework of the study protocol, but the right to publish the data will be with the research team, and if the data is published by other people, it is necessary to mention the source. People who wish to have access to data or documents should send their written request to Dr. Hadi Pourjafar's email and explain their reason for needing these data or documents and how they will use them. If a request with this theme is received, a decision will be made with the opinion of the research team and taking into account the job title of the applicant and the content of the written request sent by him.

From where data/document is obtainable
From the project manager, Dr. Hadi Pourjafar
pourjafarhadi59@gmail.com

What processes are involved for a request to access data/document
The applicant must first submit a request including the requested data or document, the reason for the need for this data or document and the uses he will make of it along with a brief introduction of himself and his company or university to Mr. Hadi Pourjafar. After submitting the application to the project manager, this application will be reviewed at the earliest opportunity and within two weeks after receiving the application in a meeting with the presence of all those involved in the project. will be provided to the applicant.

Comments