

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of self-care behavior promotion on wound healing in infectious Neuropathic diabetic ulcer

Protocol summary

Education and self-care will have better therapeutic outcomes.

Study aim

The effect of self-care behavior promotion on wound healing in infectious Neuropathic diabetic ulcer

Design

Sample size in this study is 104 diabetic patients with Neuropathic infected wound is considered. Multi-stage simple randomized sampling method is considered. They were randomly assigned to control and test groups. The criteria for entering this study is to diagnose diabetes and suffer from infected wound between age from 30 to 60 years old.

Settings and conduct

Sample size is 104 diabetic patients with Neuropathic infected wound referring to Hazrat Rasool Hospital ,Telma and Ozan clinics.They were randomly assigned to control and test groups.First, the profile and check list of self-care behavior, and IWGDF form of staging of infection are completed then based on the results of the data will be analyzed.The design of the interventions related to early completion of the questionnaire and the analysis of the results. Both groups will receive antimicrobial dressing but the resources like educational books from Endocrinology and Metabolic center of Tehran University of Medical Sciences Tehran are provided for patients without charge for Intervention group. Moreover patient will train in 4 sessions

Participants/Inclusion and exclusion criteria

Participants include 104 patients in both intervention and control groups. The criteria for entry in this study:Patients afflicted with diabetes between 30 to 60 years old, suffering Neuropathic infected wound.The exclusion criteria of this study are in contrast to the entry criteria.

Intervention groups

The intervention group:beside receiving anti-microbial dressing, will receive a self-care education book on diabetes and received 4 training sessions.The control group: only receive antimicrobial silver dressing.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150531022500N3**

Registration date: **2018-09-02, 1397/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-02, 1397/06/11**

Update count: **0**

Registration date

2018-09-02, 1397/06/11

Registrant information

Name

Farbod Ebadi Fard Azar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8861 0120

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ebadi.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-09, 1397/04/18

Expected recruitment end date

2018-10-03, 1397/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of self-care behavior promotion on wound healing in infectious Neuropathic diabetic ulcer

Public title
The effect of self-care behavior promotion on wound healing in infectious Neuropathic diabetic ulcer

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
ABI review (Ankle brachial index) Physician's approval in terms of Neuropathy situation Having an infected wound
Exclusion criteria:
Ischemic condition Not being listed in the age range

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
Multi-stage simple randomized sampling is considered. Samples were selected randomly from the patient list. Then with simple randomized assigned to control and test groups (each group was 50).

Blinding (investigator's opinion)
Single blinded

Blinding description
In the first stage, the profile and check list of self-care behavior, and IWGDF form of staging of infection are completed then based on the results of the data analysis, in first group just antimicrobial dressing will be applied whereas in second group beside applying antimicrobial dressing the training will be designed and they will receive educational books and printed documents from Endocrinology and Metabolic center of Tehran University of Medical Sciences Tehran are provided to patients without charge.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

دانشگاه علوم پزشکی ایران

Street address

Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2019-02-07, 1397/11/18

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511107004

Health conditions studied

1

Description of health condition studied

Diabetic Neuropathy infected wound

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self care

Timepoint

Self-care measurements at the beginning of the study and after the completion of the study

Method of measurement

Self care checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 52 Neuropathic diabetic patients with infected wound receiving antimicrobial dressing with training.

Category

Prevention

2

Description

Control group: 52 Neuropathic diabetic patients with infected wound wound that only received antimicrobial dressing.

Category

Treatment - Devices

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

Hazrat Rasoul Hospital

Full name of responsible person

Dr Omid Moradi Moghadam

Street address

Hazrat Rasoul Akram Medical Education hospital, Corner of Mansoori Street, Satarkhan street.

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2**Recruitment center****Name of recruitment center**

Medical Ozone

Full name of responsible person

محمد پور تقوی شهرستانی

Street address

Fourth Floor, Medical department 200, beside Tehran clinic hospital, Ghaemagham street

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3**Recruitment center****Name of recruitment center**

تلما

Full name of responsible person

محسن طریقت منفرد

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Floor 1, plaque 9, Farzin Street, Bagherhkan street.

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panyrose1381@yahoo.com

Web page address

http://telmaclinic.com/

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

Iran University of Medical Sciences

Full name of responsible person

Dr.kazem malakooti

Street address

Vice-Chancellor of Technology Research, near Milad Hospital, IUMS, Shahid Hemmat Highway

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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

Dr. Farbod Ebadi Fard Azar

Position

Professor of management and Health Services

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

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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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Person responsible for updating data

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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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

Ethically it is not acceptable for researcher

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

Individual profile, Diabetic foot evaluation, Self-care
checklist, Infection stage evaluation, Testimonial

When the data will become available and for how long

Public access will be possible after defense

To whom data/document is available

All the researchers who are interested in this topic

Under which criteria data/document could be used

Applying for accessing data from Professors or Students
in Nursing and Health Education

From where data/document is obtainable

The researcher's email

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

Sending email is enough

Comments