

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Implementation of Nurse-led Care on Quality of Care and healing of diabetic foot ulcer

Protocol summary

Study aim

Determination of implementation of Nurse-led Care on Quality of Care and healing of diabetic foot ulcer

Design

Randomized clinical trial

Settings and conduct

The purpose of the research will be explained to patients with diabetic foot ulcer that referred to Shariati hospital and written consent will be obtained. Then 20 subjects for each group were selected according to the sample size formula and divided into two groups (intervention: nursing-led and control: routine care), before and after intervention and follow-up (6 weeks and 12 weeks after intervention) Diabetic Foot Ulcer checklist and QUALPAC (Quality Patient Care Scale) questionnaire will be completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with type 1 diabetes and two diagnosed men and women 18 years of age and older diabetic patients with foot ulcer
Exclusive criteria: Patients with active foot ulcer
Patients participate in similar studies

Intervention groups

Nurse-led group: Nurse-led interventions will be done with Integrated, Interdisciplinary and Comprehensive Steps. In the Integrated phase, care delivery will be step by step and according to Guideline of care for diabetic foot ulcer. In the interdisciplinary phase, the counseling required by the treatment team will be carried out. In the Comprehensive phase, supportive and education care services will be transferred to the patient and their caregiver depending on the patient's need. Control group: The control group will be treated and provided routinely care which include control of blood sugar, appropriate antibiotic treatment if it was necessary, off loading foot ulcer, remove the foot ulcer and dressing with saline normal.

Main outcome variables

Quality of care, Remove of Diabetic foot ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100628004256N8**

Registration date: **2018-11-13, 1397/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-13, 1397/08/22**

Update count: **0**

Registration date

2018-11-13, 1397/08/22

Registrant information

Name

Nasrin Samadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 3057

Email address

na.samadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Implementation of Nurse-led Care on Quality of Care and healing of diabetic foot ulcer

Public title

Implementation of Nurse-led Care on Quality of Care and healing of diabetic foot ulcer

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with type 1 diabetes and two diagnosed men and women 18 years of age and older diabetic patients with foot ulcer

Exclusion criteria:

Patients with active foot ulcer(presence of secretions at the site of the ulcer, has an infectious smell, yellow or white ulcer) Patients participate in similar studies

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

Quality of care, measure Diabetic foot ulcer

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher will do the random assignment by blocking and using the card. Considering that 40 people should be included in the study and there will be two groups (navigator nurses and control group), taking into account all possible probabilities, 20 blocks of 6 states will be calculated.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

There is not more attribution.

Secondary Ids

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Eastern Nosrat st, Tohid esquare,Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

5619835164

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4526

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

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

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

Quality of care

Timepoint

Before intervention, 6 weeks after intervention and follow up 12 weeks after the intervention

Method of measurement

(Quality Patient Care Scale) QUALPAC

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

Healing of Diabetic foot ulcer

Timepoint

Before intervention/6 weeks after intervention And follow up 12 weeks after the intervention

Method of measurement

Wound Assessment Check list

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

Intervention group: Nurse-led interventions will be done with Integrated, Interdisciplinary and Comprehensive Steps. In the Integrated phase, care delivery will be step by step and in accordance with the Guideline, care for diabetic foot ulcer. In the interdisciplinary phase, the counseling required by the treatment team will be carried out. In the Comprehensive phase, supportive and educative as a care services will be provided to the

patient and their caregiver depending on the patient's need.

Category

Treatment - Other

2

Description

Control group: The control group will be treated and provided routinely care which include control of blood sugar, appropriate antibiotic treatment if it was necessary, off loading, remove of foot ulcer and dressing with saline normal.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics and educational hospitals under the supervision of Tehran University of Medical Sciences

Full name of responsible person

Research Deputy

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Eastern Nosreat st, Tohid esquare,Tehran,Iran.

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nasrin.samadi87@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research Deputy of school of Nursing and Midwifery

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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

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Samadi

Position

Academic Staff

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable