

# 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

**Street address**

Eastern Nosreat st, Tohid esquare, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

5619835164

**Phone**

+98 21 6692 5560

**Email**

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

**Street address**

Eastern Nosreat st, Tohid square, Tehran, Iran.

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**Province**

Tehran

**Postal code**

5619835164

**Phone**

+98 21 6692 5560

**Email**

nasrin.samadi87@yahoo.com

**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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**Email**

nasrin.samadi87@yahoo.com

**Person responsible for scientific 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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**Email**  
nasrin.samadi87@yahoo.com

## Person responsible for updating data

### 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  
**Street address**  
Eastern Nosreat st, Tohid square, Tehran, Iran.  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**  
5619835164  
**Phone**  
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**Email**  
nasrin.samadi87@yahoo.com

## 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