

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effectiveness of hospital-based home care compared to hospital-based care for diabetic foot patients on their quality of life and duration of wound healing in Shariati hospital

Protocol summary

Summary

Present study will be conducted as an interventional study in the form of nonequivalent to compare outcomes between two treatment modalities. In this study we will examine effectiveness and costs associated with adopting / implementing a new policy in Iran: "hospital-based home care". Study's sample includes patients with diabetic foot ulcers admitted to a teaching - referral hospital who after being assessed by the researchers are identified to have the inclusion criteria for the study such as decision of the physician to continue therapeutic process at home, having diabetic foot ulcers (based on Wegener classification system for foot wounds in grade 2, 3, 4 and ABI> 0, 5); patient's residency in Tehran, and the patient's consent. Patients who have the criteria are randomly assigned to the control or intervention group. in both groups, outcome indicators of the study include rate of HbA1c, patient's insulin regimen, rate of amputation, wound class, length of stay, patient satisfaction and quality of life. To determine whether two modalities have a significant difference in time of recovery (minimum error of 5%- and - power of 90%), the sample size was determined to include 120 patients, using a systematic sampling technique (30 patients in HBHC and 90 patients HBC). After including patients in the HBHC modality, they are trained about the process and purpose of the study, given an informed consent, introduced to home care providers, discharged from hospital and admitted to the HBHC.

General information

Acronym

Hospital-based home care compared to hospital-based care

IRCT registration information

IRCT registration number: **IRCT2017080935600N1**

Registration date: **2017-08-15, 1396/05/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-15, 1396/05/24

Registrant information

Name

Mohamadreza Jafary

Name of organization / entity

Tehran uneversity of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ministry of Health and Medical Education; Endocrinology and Metabolism Research Institute

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of hospital-based home care compared to

hospital-based care for diabetic foot patients on their quality of life and duration of wound healing in Shariati hospital

Public title

Effectiveness of hospital-based home care compared to hospital-based care for diabetic foot patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patient has given informed consent to participate within the study; the patient has a primary diagnosis of DF (stage 2,3,4 and ABI >0.5); the patient's physician must agree that the patient is suitable for early discharge to HBHC; possibility to reside in Tehran, Iran. Exclusion criteria: unstable patient; the patient's physician order that the patient should be transport to hospital; the patient hasn't given informed consent.

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Committe in Resarech afiliated of Endocrinology and Metabolism Research Institute

Street address

Endocrinology and Metabolism Research Institute, Shariati hospital, at the begining of Jalale Al Ahmad avenue, Kargar's north street, Tehran, Iran

City

Tehran

Postal code

1411713137

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.TUMS.EMRI.REC.1395.0081

Health conditions studied

1

Description of health condition studied

Diabetic Foot Ulcer

ICD-10 code

E10.5

ICD-10 code description

Diabetes mellitus with peripheral circulatory complications

Primary outcomes

1

Description

Duration of wound healing

Timepoint

One mounth after intervention

Method of measurement

Patient interview, screening of medical record

Secondary outcomes

1

Description

Length of stay

Timepoint

18 mounths after intervention

Method of measurement

Screening of patient record

2

Description

Patient quality of life

Timepoint

18 mounths after intervention

Method of measurement

Patient interview

3

Description

Level of HbA1c

Timepoint

18 mounths after intervention

Method of measurement

Screening of patient record

4

Description

Rate of patient satisfaction

Timepoint

One mounth after intervention

Method of measurement

patient interview

5

Description

Rate of amputation

Timepoint

18 months after intervention

Method of measurement

Patient visit and screening of medical record

Intervention groups

1

Description

Treatment of patients under intervention is continued in their home, having their family support, by a company licensed by Iran's Ministry of Health, consisting of specialized physician(s) and nurse(s). The patients' home care process is monitored and controlled by the study group through direct observation in patients home, 2 times a week (according to the timetable of the study). Patients will receive the treatment according to the clinical guidelines for wound management in diabetic foot ulcers approved by the endocrinology and metabolism research center.

Category

Treatment - Other

2

Description

Patients in the control group receive usual care in hospital

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Mohamadreza Jafary

Street address

Shariati hospital, at the beginning of Jalale Al Ahmad avenue, Kargar's north street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute

Full name of responsible person

Dr. Mohammad reza Mohajeri

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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

Endocrinology and Metabolism Research Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zhila Najafpour

Position

PhD Health Care Management

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shariati Hospital

Full name of responsible person

Dr. Mohamadreza Jafary

Position

General practitioner

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty