

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Study of the Effect of Foot Reflexology in Patients with Type II Diabetes Undergoing Hemodialysis on Blood Sugar and HbA1C Level

Protocol summary

Study aim

Study of the effect of foot reflexology on blood sugar and HbA1c levels in type II diabetic patients undergoing hemodialysis

Design

This double-blind study was conducted on 70 hemodialysis patients with diabetes. In this clinical trial, the subjects were randomly divided into two equal groups of 35 controls and intervention.

Settings and conduct

In order to investigate the effect of foot reflexology on blood glucose and glycosylated hemoglobin in Arak Hami's hemodialysis center, 70 patients were randomly divided into two groups of 35 subjects randomly. In this double blind, patient, and data analyst, there was no information about how people were placed in the two groups. For the intervention group, reflexology was performed for a period of three months during hemodialysis. Blood sugar was measured before and after dialysis for 3 months and glycosylated hemoglobin before and after 3 months after the intervention. In the intervention group, only blood sugar and glycosylated hemoglobin tests were performed as in the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having written and informed consent 2- No diabetic foot ulcer or infection in massage areas. 3- At least 3 years from the start of diagnosis of diabetes. 4- Have a minimum age of 30 and a maximum of 70 years. 5. Lack of skin diseases such as yellow wounds and ... Exclusion criteria: 1- Type 1 diabetes 2- History of participation in complementary therapies such as reflexology and ... up to six months ago 3- Having coagulation disorders 4. Unwillingness to continue cooperation 5-Mortality or Immigration

Intervention groups

The intervention group included 35 hemodialysis patients with type 2 diabetes, that Reflexology was performed for 3 months. The control group included 35 patients who

did not receive any intervention.

Main outcome variables

Blood sugar, HbA1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190617043910N1**

Registration date: **2019-09-27, 1398/07/05**

Registration timing: **retrospective**

Last update: **2019-09-27, 1398/07/05**

Update count: **0**

Registration date

2019-09-27, 1398/07/05

Registrant information

Name

Sima Zahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

s_zahedi20@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-03-01, 1396/12/10

Actual recruitment start date

2018-12-01, 1397/09/10

Actual recruitment end date

2019-03-01, 1397/12/10

Trial completion date
2019-03-01, 1397/12/10

Scientific title
Study of the Effect of Foot Reflexology in Patients with Type II Diabetes Undergoing Hemodialysis on Blood Sugar and HbA1C Level

Public title
The Effect of Foot Reflexology in Patients with Type II Diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having written and informed consent. No diabetic foot ulcer or infection in massage areas At least 3 years from the start of diagnosis of diabetes. Have a minimum age of 30 and a maximum of 70 At least 3 years after the diagnosis of Renal failure Lack of skin diseases such as impetigo and ...
Exclusion criteria:
Type 1 diabetes History of participation in complementary therapies such as massage, reflexology and ... up to six months ago Having coagulation disorders such as thrombocytopenia, warfarin poisoning and ... Unwillingness to continue cooperation mortality or Immigration

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, simple randomization method was used to determine the control and intervention groups. In this way, 70 sheets were put inside a box, 35 of which were written I as intervention and the other 35 were written C as control. The box was then given to the patients to select one patient from each box with their eyes closed.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this one-blind study, the data analyzer does not know which control group and which intervention. But participants in the research, the researcher, the interventionist, and those involved in the preparation of the proposal are fully aware of the control and intervention groups. Also, the Committee on Safety and Data Monitoring has no role in the present trial.

Placebo

Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

sardasht- basij square

City

arak

Province

Markazi

Postal code

3819693345

Approval date

2018-01-21, 1396/11/01

Ethics committee reference number

IR.ARAKMU.REC.1396.274

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

IV

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

level of blood sugar

Timepoint

Measure of blood sugar levels before and after each intervention session, three times a week for three months

Method of measurement

Glucometer

2

Description

Glycated hemoglobin

Timepoint

Before and after the intervention

Method of measurement

blood sample with Elisa kit

Secondary outcomes

empty

Intervention groups

1

Description

70 participants were randomly divided into intervention and control groups. Intervention group: 35 patients with diabetes undergoing hemodialysis, undergoing foot reflexology for 10 minutes per foot for 3 months and 3 times per week at bedtime, in supine position, with pillow. The head and one of the knees were placed in a gentle, normal environment at 20 to 24 ° C. Before the intervention, warm water was used to increase foot freshness. The towels were then dried with a towel and the odor-softening lotion was applied before the start of the reflection massage to relax the legs. Evaluation of blood glucose in two stages: 1- Before the intervention, 2- After the intervention with glucometer for three months and evaluation of glycosylated hemoglobin in two stages: 1- Before the intervention and 2- Three months after the intervention accepted.

Category

Treatment - Other

2

Description

Control group: 35 patients with diabetes were treated with hemodialysis for which no intervention or reflexology was performed, but routine blood glucose control treatments such as exercise, diet and medication regimens were continued as usual and blood glucose testing was continued. Glycated hemoglobin was used as the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hami Hemodialysis Center

Full name of responsible person

Sima Zahedi

Street address

sardasht, basij square

City

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3819693345

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Email

s_zahedi20@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

sima zahedi

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Email

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

sima zahedi

Position

instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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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Position

instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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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

Unnamed participants' data includes demographic information, the primary and secondary outcome of sharing.

When the data will become available and for how long

Start access after publishing the article for 6 months

To whom data/document is available

Participants in the research project

Under which criteria data/document could be used

If the participants tend to be aware of the results of the study

From where data/document is obtainable

Corresponding Author

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

he applicant can access the results two weeks after the request, with written request and contact with the Corresponding author after complying with the hierarchy.

Comments