Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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sardasht, basij square
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
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s_zahedi20@yahoo.com
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
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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