

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the Effect of Computerized Custom Insole with Custom-fit Insole on the Function and Quality of Life in Elderly diabetic.

Protocol summary

Study aim

Comparison of the Effect of Computerized Custom Insole with Custom-fit Insole on the Function and Quality of Life in Elderly diabetic.

Design

A clinical trial with a control group, with parallel groups, A blind strai, randomized

Settings and conduct

Elderly study inclusion criteria to participate in the study as soon as they complete two questionnaires used in the study. After a mean period of 4-6 weeks, the questionnaire will again be available to patients by telephone or in person. After completing the questionnaires, in data analysis, pre-test and post-test will compare differences between foot and ankle and quality of life of each group, and also compare foot and ankle and quality of life of the two groups. accepted. Individuals will be unaware of the difference between the two groups.

Participants/Inclusion and exclusion criteria

Age between 60 and 75 years old; confirmation of diabetes and neuropathy by a specialist; physician approval to receive insole orthoses; absence of diabetic ulcer; ability to walk; minimum literacy for answering questionnaires. Exclusion criteria: unwillingness to use orthoses during research; unwillingness to pursue research; failure to answer more than 10% of the questionnaire questions.

Intervention groups

The test group of computerized custom insole receives.
The control group custom-fit Insole receives

Main outcome variables

Quality of life, the foot and ankle pain, function, Alaymnt

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140219016643N6**

Registration date: **2019-09-24, 1398/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Behshid Farahmand

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

farahmand.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2019-11-01, 1398/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Computerized Custom Insole with Custom-fit Insole on the Function and Quality of Life in Elderly diabetic.

Public title

Comparison of the Effect of Computerized Custom Insole with Custom-fit Insole on the Function and Quality of Life in Elderly diabetic.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 60 to 75 years Diabetic patients with peripheral neuropathy Physician approval to receive medical insole Without diabetic foot ulcer Ability to walk independently Minimum literacy for answering questionnaires

Exclusion criteria:

Do not use medical insole during follow-up Failure to answer more than 10% of the questionnaire questions Unwillingness to continue follow-up

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants who refer to the Orthotics and Prosthetics Center are simple non-randomly divided in to Computerized Custom Insole and Custom-fit Insole groups. Insole type is written on paper and put in envelope. Each participant picks up one envelope. The envelope was opened by an expert orthotics and prosthetics and appropriate insole is made.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only participants are kept blind in this study. Participants placed into the Computerized Custom Insole or Custom-fit Insole groups based on the envelopes they have taken. Foot pressure was evaluated in all participants but these data is only used in the Computerized Custom Insole group. Also, the foot size of all patients is checked and these data is only used in the Custom-fit Insole group. The appearance, structure and material of the insoles are the same in the both groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Mother Square, Abkar Shahnazari Street, Madadkaran Street, Faculty of Rehabilitation Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Approval date

2019-08-31, 1398/06/09

Ethics committee reference number

IR.IUMS.REC.1398.496

Health conditions studied

1

Description of health condition studied

Elderly with type 1 and type 2 diabetes

ICD-10 code

E08.00

ICD-10 code description

Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)

Primary outcomes

1

Description

The Persian version of the Diabetes Quality of Life Questionnaire (DQOL) will be used to assess the quality of life in diabetic elderly.

Timepoint

Quality of life score is predicted before intervention 50 and after intervention 60.

Method of measurement

The Persian version of the Diabetes Quality of Life Questionnaire (DQOL) will be used to assess the quality of life in diabetic elderly.

2

Description

The Persian version of the American Foot and Ankle Assessment Questionnaire (AOFAS) will be used to evaluate the performance of the diabetic foot and ankle complex.

Timepoint

Foot and ankle performance score is predicted before intervention 50 and after intervention 75.

Method of measurement

The Persian version of the American Foot and Ankle

Assessment Questionnaire (AOFAS) will be used to evaluate the performance of the diabetic foot and ankle complex.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients in the test group are custom-made foam computer-manufactured insoles. To fabricate CAD-CAM insoles, these individuals were individually scanned with a Guy Capron device.

Category

Treatment - Devices

2

Description

Control group: All patients in the control group are made of custom-made insole.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Technical orthopedic mehr

Full name of responsible person

Mohammad Javad Hojati

Street address

Yazd city-Boulevard waiting for al-Qaem

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8941776445

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mohammad.javad7@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Kazem Malakoti

Street address

Hemat Highway, next to Milad Tower, Iran University of Medical Sciences

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1449614535

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research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Behshid Farahmand

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics & Prosthetics

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Position

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Comparison of the Effect of Computerized Custom Insole with Custom-fit Insole on the Function and Quality of Life in Elderly diabetic.

When the data will become available and for how long

All study data are shareable after deleting the profile and contact number of the participants

To whom data/document is available

Accessibility for all people

Under which criteria data/document could be used

Do not consider a particular item.

From where data/document is obtainable

Contact by e-mail of corresponding author

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

If there is no precautionary statement from the journal which the article is printed, with contact by e-mail of corresponding author, information will be sent to the requesting person within less than one month

Comments