

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of diabetic socks on plantar pressure distribution in people with diabetic neuropathy .

Protocol summary

Summary

Object: the effect of diabetic socks on plantar pressure distribution in people with diabetic neuropathy. Study design: the study is an experimental study in type of time series. Study population: patients with diabetic neuropathy. Inclusion criteria: women or men with type II diabetes based on WHO criteria; age in the range of 35 to 85 years of old and period of diabetes between 11-32 years; the absence of previous wounds in the leg and based on clinical examination (degree of zero based on maggitt wagner index); no history of medical use of shoes or insoles; the risk of neuropathy and the inability to detect Monofilaments with a diameter of 5.07 or Pressure of 10 grams using the Semmes Weinstein Monofilaments. Exclusion criteria: inability to walk for any reason. Sample size: 25. Intervention: diabetic socks. The primary outcome or study outcomes: determine the pressure foot with diabetic neuropathy before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051515329N2**

Registration date: **2016-07-11, 1395/04/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name

Sedigheh sadat Mirbagheri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 1572

Email address

s.mirbagheri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of diabetic socks on plantar pressure distribution in people with diabetic neuropathy .

Public title

The effect of diabetic socks on plantar pressure in people with diabete.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: female or male with type 2 diabetes according to WHO criteria; age between 35 - 85 years old and duration of diabetes between 11- 32 years; absence of previous wounds in the leg and wound based on clinical examination (zero based on Meggitt Wagner); neuropathy and inability to recognize Monofilament with a diameter of 5.07 or 10 grams pressure using the Semmes Weinstein Monofilaments; no history of medical use of shoes or insoles. Exclusion criteria: need for

walking aids; non-diabetes-related pain or injury in the leg while walking; foot ulcer causes other than diabetes; Charcot neuropathy with clinical symptoms such as unilateral swelling, increase in skin temperature, arrhythmia and joint effusion; severe deformity such as Claw toe and Hammer toe to prevent wearing standard shoe.

Age

From **35 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hamadan University of Medical Sciences.

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street.

City

Hamadan

Postal code**Approval date**

2016-06-23, 1395/04/03

Ethics committee reference number

IR.UMSHA.REC.1395.124

Health conditions studied**1****Description of health condition studied**

Diabete mellitus type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Max plantar pressure

Timepoint

Before and after intervention

Method of measurement

Foot pressure measuring system

Secondary outcomes

empty

Intervention groups**1****Description**

Using diabetic socks.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam khomeini clinic

Full name of responsible person**Street address****City**

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research and technology

Full name of responsible person

Saeed Bashirian

Street address

Vice chancellor for research and technology,
University of medical sciences, Shahid Fahmideh
Street, Hamadan.

City

Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research and technology

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*

Hamadan

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

School of Rehabilitation

Full name of responsible person

Sedigheh Sadat Mirbagheri

Position

Faculty/ Master of Science

Other areas of specialty/work**Street address**

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City**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*