

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of warm foot bath on neuropathy and fatigue in elderly patients with diabetes mellitus

Protocol summary

Study aim

Determine the effect of warm foot bath on the mean neuropathy of elderly people with diabetes; Determine the effect of warm foot bath on the mean score of fatigue in elderly people with diabetes;

Design

Two arm parallel group randomised trial with One Blind postoperative care and outcome assessment

Settings and conduct

Empirical study, the Diabetes Research Center of Yazd city. One-way blindness is done in participants and analyzers.

Participants/Inclusion and exclusion criteria

Significance of inclusion: People over 60 years of age referred to the Diabetes Research Center of Yazd, having diabetes and sensory neuropathy and earning a minimum score of 6 in the Michigan Questionnaire or 3 from the Michigan Examination Department, earning a minimum score of 4 in the Piper Fatigue Scale, Frequent and informed consent to participate in the study, lack of illness or conditions affecting neuropathy (cerebral stroke, multiple sclerosis, gout, Parkinson's, spinal cord injury, Guillain Barre, rheumatic disease with the approval of a neurologist, alcohol and smoking) ; Exit criteria: Skin diseases such as eczema and any lesions in the legs and cognitive impairment and moderate to severe depression; Deep vein thrombosis, proven or suspected to deep vein thrombosis and varicose veins;

Intervention groups

1. No intervention in the control group 2. Perform 8 sessions of hot foot bathing for one day during the 2 weeks during the presence of the elderly in the center for 20 minutes immersion in both feet at $40 \pm 2^\circ \text{C}$ and determining the mean neuropathy and fatigue Intervention group samples were taken two weeks and one month later

Main outcome variables

neuropathy, fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171217037931N1**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-07, 1397/02/17**

Update count: **0**

Registration date

2018-05-07, 1397/02/17

Registrant information

Name

SEDIGHEH MOKHTARI HASAN ABAD

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3522 9466

Email address

s.mokhtari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-24, 1396/10/03

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of warm foot bath on neuropathy and fatigue in elderly patients with diabetes mellitus		Medical Sciences, Yazd
Public title	Effect of warm foot bath on neuropathy and fatigue in diabetic elderly	Street address NO.8917774894, Faculty of Nursing and Midwifery, Bou Ali Ave, Tayyasar Fallahi Blvd, Safayeh, Yazd Town
Purpose	Supportive	City yazd
Inclusion/Exclusion criteria	Inclusion criteria: People over 60 years of age referred to the Diabetes Research Center of Yazd diabetes sensory neuropathy, and earning a minimum score of 6 in the Michigan Questionnaire or 3 from the Michigan Examination Department earning a minimum score of 4 in the Piper Fatigue Scale lack of illness or conditions affecting neuropathy (stroke, multiple sclerosis, gout, Parkinson's, spinal cord injury, Guillain Barre, rheumatic disease approved by a neurologist, alcohol and smoking) informed consent for Participate in the study Exclusion criteria: Diseases of the skin such as eczema and any lesions in the legs cognitive impairment and moderate to severe depression deep vein thrombosis, proven or suspected to deep vein thrombosis and varicose veins	Province Yazd
Age	From 60 years old	Postal code 8917774894
Gender	Both	Approval date 2017-11-25, 1396/09/04
Phase	N/A	Ethics committee reference number IR.SSU.REC.1396.144
Groups that have been masked	Data analyser	Health conditions studied
Sample size	Target sample size: 70	1
Randomization (investigator's opinion)	Randomized	Description of health condition studied Diabetes
Randomization description	Simple randomization, random number table tool, individual randomization unit	ICD-10 code E08.21
Blinding (investigator's opinion)	Not blinded	ICD-10 code description Diabetes mellitus due to underlying condition with diabetic nephropathy
Blinding description	Data analyzer is a one-way blind	2
Placebo	Not used	Description of health condition studied Sensory Neuropathy
Assignment	Parallel	ICD-10 code E08.40
Other design features		ICD-10 code description Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified
Secondary Ids	empty	Primary outcomes
Ethics committees		1
1		Description Sensory neuropathy
Ethics committee		Timepoint Take the study 15 days and one month after the start
Name of ethics committee	Ethics Committee of Shahid Sadoughi University of	Method of measurement Michigan questionnaire
		2
		Description Fatigue
		Timepoint Take the study 15 days and one month after the start
		Method of measurement Piper Fatigue Questionnaire
		Secondary outcomes
		empty

Intervention groups

1

Description

Intervention group: Foot warm bath, 8 sessions of immersion feet in water at a temperature of 42-38 ° C for 20 minutes

Category

Treatment - Other

2

Description

Control group: No intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Dr. Masoud Rahmanian

Street address

NO.8917693571,Honar Hall Ave, shahid sadoughi Blvd,Yazd Town

City

Yazd

Province

Yazd

Postal code

8917774894

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+98 35 3728 0228

Fax

+98 35 3728 0216

Email

drc@ssu.ac.ir

Web page address

<http://ssu.ac.ir/cms/index.php?id=1287>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Behnaz Anjzab

Street address

NO,8917693571,Faculty of Midwifery Nursing, Buali Ave,fallahi Blvd,Safaeiyeh, Yazd Town

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Email

info@ssu.ac.ir

Web page address

<http://www.ssu.ac.ir/cms/index.php?id=287>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Sedigheh Mokhtari Hasan abad

Position

Graduate Student, Senior Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

NO.8917774894,Faculty of Nursing and Midwifery, Bou Ali Ave, Tayyasar Fallahi Blvd, Safayeh, Yazd Town

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S.MOKHTARI@SSU.AC.IR

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sedigheh Mokhtari Hasan Abad

Position

Graduate Student, Senior Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

NO,8917774894, Faculty of Midwifery Nursing, Buali Ave, Fallahi timsar Blvd, Safaeiyeh, Yazd Town

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sedigheh mokhtari hassan abad

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

NO.8917774894, Faculty of Nursing and Midwifery, Bou Ali Ave, Tayyasar Fallahi Blvd, Safayeh, Yazd Town

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Email

s.mokhtari@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The study protocol will be shared as an article. Data analysis will be shared as an article after the end of the study. The informed consent form will be sent by email to the requesting parties. A clinical study report will be shared through the article. The SPSS file is sent via email in the data sorting system.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will be available to researchers working in academic and academic institutions.

Under which criteria data/document could be used

Presenting / documenting studies in research centers and universities related to aging, complications of chronic diseases, diabetes, and thermotherapy to prevent further studies.

From where data/document is obtainable

Sedigheh Mokhtari Hassan Abad-
Mokhtari13581979@gmail.com- Mobile 09304079986
Address: NO.4, Danesh Ave, Kargar Blvd, Emamshahr, phone 03535229466

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

Applicants will send their application by e-mail and within a maximum of one week the requested items will be sent.

Comments

This clinical study was conducted to determine the effect of warm foot bath on neuropathy and fatigue in elderly patients with diabetes referred to the Yazd Research Center. All parts of the study, except for the names of the participants, can be published.