

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Local Heat Therapy on Peripheral Neuropathy Symptoms in Patients Type 2 Diabetes

Protocol summary

Study aim

Determine the Effect of Local Therapy on the Clinical Signs of Peripheral Neuropathy in Patients with Type 2 Diabetes

Design

Randomized clinical trial with two groups (intervention and control), not blind, and parallel groups

Settings and conduct

This study was a randomized clinical trial. Patients were divided into intervention and placebo groups based on permutation blocks. The sample size was 26 patients in each group and the place of research of the specialized clinic and diabetes of Allameh Behnouli Hospital in Gonabadi. The intervention group and the placebo chemotherapy were performed twice a day and 20 minutes each time for a week. In the placebo group, the Hot Pack was similar to the non-warm-up intervention group.

Participants/Inclusion and exclusion criteria

Entry criteria: Patient with type 2 diabetes with complications of neuropathy The patient's desire and informed consent to participate in the study Having neuropathic pain due to NPS scale and sensory impairment in the form of numbness and paresthesia Awareness and the power of speaking and communication to report the severity of clinical symptoms during examination Age under 65 years Non-Entry criteria: The disease or conditions affecting neuropathy with the approval of a neurologist (multiple sclerosis, gout, Parkinson's, spinal cord injury, Guillain Barre, rheumatic disease) Deep vein thrombosis Proven or suspected venous thrombosis The presence of arrhythmias of the heart

Intervention groups

Patients in the intervention group received heat therapy using warm packets heated to 40 ° C and at the end of the tibial nerve pathway in the lower third of the legs and feet twice a day, and each 20 minutes for one week. . In the placebo group, the same time the Hot Pack was

similar to the intervention group without heating twice a day (one morning in one evening) for one week.

Main outcome variables

Clinical signs of neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181015041354N1**

Registration date: **2018-10-27, 1397/08/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-27, 1397/08/05**

Update count: **0**

Registration date

2018-10-27, 1397/08/05

Registrant information

Name

Mahnaz Parimo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5725 5131

Email address

parimo.m.stu@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Local Heat Therapy on Peripheral Neuropathy Symptoms in Patients Type 2 Diabetes

Public title

The Effect of Local Heat Therapy on Peripheral Neuropathy Symptoms

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with type 2 diabetes with complications of neuropathy The patient's desire and informed consent to participate in the study Having neuropathic pain due to NPS scale and sensory impairment in the form of numbness and paresthesia Awareness and the power of speaking and communication to report the severity of clinical symptoms during examination Age under 65 years

Exclusion criteria:

The disease or conditions affecting neuropathy with the approval of a neurologist (multiple sclerosis, gout, Parkinson's, spinal cord injury, Guillain Barre, rheumatic disease) Deep vein thrombosis Proven or suspected venous thrombosis The presence of arrhythmias of the heart

AgeTo **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **52****Randomization (investigator's opinion)**

Randomized

Randomization description

The research units were selected on the basis of text input criteria and randomly assigned to four groups of permutation blocks in two groups of intervention and placebo.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Gonabad University of Medical Sciences

Street address

Research & Technology Dept, Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2018-08-08, 1397/05/17

Ethics committee reference number

IR.GMU.REC.1397.002

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

Diabetic neuropathy

ICD-10 code

G99.0

ICD-10 code description

Autonomic neuropathy in diseases classified elsewhere

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

The severity of clinical symptoms of diabetic neuropathy

Timepoint

Before the intervention and two days after the end of the intervention period

Method of measurement

Neuropathy Symptom Score

Secondary outcomes

empty

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

Intervention group: Patients in the intervention group received heat therapy using warm packets heated to 40 ° C and at the end of the tibial nerve pathway in the lower third of the legs and feet twice a day, and each 20 minutes for one week

Category

Other

2

Description

Intervention group: Simultaneous use of HotPack is quite similar to the intervention group without heating twice a day (one morning, one evening) for one week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Bohlol Gonabadi Hospital

Full name of responsible person

Mahnaz Parimo

Street address

Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street,
Gonabad City

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6828

Email

parimo.m.stu@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Seyed Ali Sajjadi

Street address

Research & Technology Dept, Gonabad University of
Medical Sciences, Asian Roads, Gonabad, Khorasan
Razavi

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 0805

Email

sa_1344@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Mahnaz Parimo

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street,
Gonabad City

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 939 878 6461

Email

parimo.m.stu@gmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mahnaz Parimo

Position

Nurse

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9691797852

Phone

+98 939 878 6461

Email

parimo.m.stu@gmu.ac.ir

+98 51 5725 6490

Email

parimo.m.stu@gmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Mahnaz Parimo

Position

nurse

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Street address

Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street,
Gonabad City

City

Gonabad

Province

Razavi Khorasan

Postal code

96981-48471

Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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