Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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
Age
To **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
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Bohlol Gonabadi Hospital, Vahdat Blvd, Sadi Street, Gonabad City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Seyed Ali Sajjadi
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Research & Technology Dept, Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi
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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
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Person responsible for updating data

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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