Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of lower limb vibration therapy on neuropathic pain in diabetic patients

Protocol summary

Summary

Diabetic peripheral neuropathy (DPN) is one of the most common causes of morbidity and mortality in patients with diabetes and in many patients with diabetic neuropathy, pain extends as a symptom. Whole body vibration is non-invasive and has no known side effects, it is therefore important for the vibration therapy as an alternative medicine approach is clear. This research aimed to determined effect of lower extremity vibration therapy on Diabetic neuropathic pain and with relief pain of these patients, quality of life and ability to participate in daily activities, improved. This study was A clinical trial of a group before and after and in this study at first visit lower extremity neuropathy in 36 diabetic patients was meseared by clinical examination and assessment system and then His neuropathic pain was measured with VAS tool by helping the researcher. In the next stage of demographic form completed by the patient and vibration therapy in patients with neuropathy is part of the body, and each time, 2 times a day for 10 minutes (for 2 weeks) was performed. Therapy vibrator made in Japan by mechanical vibration frequency was 20 Hz and finally after two weeks of intervention Pain was measured with VAS tool. Inclusion criteria:diagnosis of diabetic neuropathy in the lower extremities,no history of any of Vibration Therapy,no history of neurological diseases such as stroke.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062310076N2**
Registration date: **2012-09-16, 1391/06/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Arak,Sardasht,Arak University of Medical Sciences, Research vice-chancellor

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lower limb vibration therapy on neuropathic pain in diabetic patients

Public title

The effect of vibration therapy on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of diabetic neuropathy in the

lower extremities, according to a rating system based on clinical symptoms and examination (by a physician, neurologist); no history of any of Vibration Therapy; no receive pain medication or drugs affecting Vibration Therapy; lack of neurological diseases such as stroke, as well as any conditions that may impact on neuropathy (multiple sclerosis, gout, Parkinson's, spinal cord injury, Barre, rheumatic disease), and this is confirmed by a doctor, a neurologist; proven having mental illness (with doctor's approval citing cases) and minimum score of 1 neuropathic pain according to VAS scale. Exclusion criterion: patients who are unable to work due to the project intervention.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

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
Arak University of Medical Sciences Ethics Committee

Street address
Arak University of Medical Sciences

City
Arak

Postal code

Approval date
2011-10-23, 1390/08/01

Ethics committee reference number
8-115-90

Health conditions studied

1

Description of health condition studied
diabetic neuropathy

ICD-10 code
E14

ICD-10 code description
With neurological complication

Primary outcomes

1

Description
Pain

Timepoint
Before intervention, one week after intervention, 2week after intervention and 3 days after the end of intervention.

Method of measurement
Visual analogous scale scale

Secondary outcomes

empty

Intervention groups

1

Description
vibrattion therapy

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin hospital

Full name of responsible person

Street address

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences,Vice Chancellor for Research

Full name of responsible person
Dr Davood Hekmatpou

Street address
Vice Chancellor for Research,Arak University of Medical Sciences, Arak

City
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences,Vice Chancellor for Research
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

Person responsible for general inquiries

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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