Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of perineural hypertonic saline injection versus acupoints of foot in the management of diabetic neuropathy: a randomized clinical trial

Protocol summary

Study aim
To evaluate the effect of perineural and acupoints hypertonic saline5% injection in diabetic neuropathy

Design
A double blinded randomized controlled clinical trial with a parallel group design of 30 patients. Randomization sequence was created by the computer with the block size of six.

Settings and conduct
In this study, 30 patients with diabetic neuropathy who are eligible for entering the study will be randomly divided into two groups of 15, in the first group heypertonic saline is injected perineural and in the second group at the site of acupoints.Both the patients and analyzer are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diabetic patients with neuropathic pain in the past 3 months, ages between 30-60 years
Exclusion criteria: any infection, tumor or cutaneous lesions at or near sites of injection, significant foot deformity, history of chemotherapy, pregnancy, lumbosacral canal stenosis, discopathy, trauma, collagen vascular disease, nerve injury or other types of neuropathy, history of coagulopathy or bleeding tendency and allergy to the medication used in trial

Intervention groups
The first group will receive hypertonic saline injection near the nerves of Sural, Peroneal and Tibial. In the second group hypertonic saline will be injected at the site of acupoints(St-44, ST41, GB-40)

Main outcome variables
Main outcome measures include neuropathy and the score of Douleur Neuropathique 4 questionnaire(DN4)

General information

Reason for update
We encountered an unexpected problem in publishing the manuscript due to error in recording the dates.

Acronym

IRCT registration information
IRCT registration number: **IRCT20170517034008N1**
Registration date: **2019-04-07, 1398/01/18**
Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**
Update count: **1**

Registration date
2019-04-07, 1398/01/18

Registrant information

Name
Nina Heidari

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
2019-04-09, 1398/01/20

Expected recruitment end date
2019-11-11, 1398/08/20

Actual recruitment start date
2019-04-09, 1398/01/20

Actual recruitment end date
2020-01-29, 1398/11/09

Trial completion date
2020-02-19, 1398/11/30

Scientific title
Efficacy of perineural hypertonic saline injection versus acupoints of foot in the management of diabetic neuropathy: a randomized clinical trial

Public title
Effect of hypertonic saline injection in diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of pain, paresthesia and sympoms of diabetic neuropathy over the past month Ages between 30-60 Complete and sign written consent
Exclusion criteria:
Infection, tumor or any skin lesions at the site of intervention Severe foot deformity History of chemotherapy Pregnancy Lumbosacral canal stenosis or discopathy Trauma Rheumatologic and collagen vascular disease(CVD) Spinal cord injury(SCI) Traumatic brain injury(TBI) Cerebrovascular accident(CVA) Other nerve injuries and neuropathies History of coagulopathy disorders History of allergy to the drugs being used in the study
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Thirty eligible patients will be randomly allocated to two parallel groups (Perineural injection group or G1 and acupoints injection group or G2). Randomization sequence is created using Excel 2007 (Microsoft) with a random block size of six.
Blinding (investigator's opinion)
Double blinded
Blinding description
We will perform a double blinded study. In both groups there are equal volume and appearance of the drug and the patients have no ideas about injection sites of the groups. Also the analyst does not have any knowledge about the type of intervention in each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
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7134814336
Approval date
2018-06-18, 1397/03/28
Ethics committee reference number
IR.SUMS.MED.REC.1397.132

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
E08.40
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
The primary outcome is an assessment tool for neuropathic pain, called Douleur Neuropathique 4 questionnaire(DN4) score.
Timepoint
For each subject, the Douleur Neuropathique 4 questionnaire outcome measure is completed at baseline, first, second and 8th week after treatment.
Method of measurement
Douleur Neuropathique 4 questionnaire to assess neuropathic pain.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The study solution consisted of 5 mL sodium chloride hypertonic 5% and 1 mL lidocaine 2% (Pasteur institute of Iran) was injected with a 27-gauge needle near the tibial, saphenous and sural nerves

(based on anatomical landmarks) under sterile condition.(Two milliliters of the study solution were injected in each point.)

Category

Rehabilitation

2

Description

Intervention group 2: we defined three acupuncture points based on the relevant literature, including ST-41, ST-44 and GB-40.The study solution consisted of 5 mL sodium chloride hypertonic 5% and 1 mL lidocaine 2% (Pasteur institute of Iran) was injected with a 27-gauge needle and two milliliters in each point.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi hospital

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Sponsors / Funding sources

1

Sponsor

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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

Shiraz 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
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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