Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of prolotherapy in perineural points and lower extremity acupoints on neuropathic pain in patients with neuropathy

Protocol summary

Study aim
Evaluation of the effect of prolotherapy injection in perineural points versus lower limb acupuncture points on neuropathic pain in patients with neuropathy

Design
Randomized clinical trial with control group, with parallel groups, double-blind, phase 3, total of 48 patients, computer-randomized with random permutation block

Settings and conduct
A total of 48 eligible neuropathic patients are blindly divided into 3 groups. In the first group, 5% dextrose around the 3 peripheral nerves of the foot, in the second group, 5% dextrose injection around the 3 acupoints of the foot, and in the control group, no injections are given. Injections are weekly for 3 consecutive weeks. All three groups are given oral pregabalin 75 mg twice daily. All patients and data analyzer are blinded at all stages of the study

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with lower extremity neuropathy aged 30 to 60 years who have not improved with conventional treatments, and they have signed a written consent form Exclusion criteria: Any tumor or infection or skin lesions at the injection site, Pregnancy, Bleeding disorders, History of prolotherapy drugs allergies

Intervention groups
In the intervention group 1, 5% dextrose is injected around 3 nerves of the foot, tibial sural and saphenous. Includes 16 people. Intervention group 2: 5% dextrose injection in 3 acupoints of foot, GB40, ST41 and ST44, including 16 people. Control group: without injection, including 16 people All patients receive oral pregabalin 75 mg twice daily

Main outcome variables
Douleur Neuropathique 4 questionnaire (DN4) and the Overall Neuropathy Limitations Scale (ONLS) score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210309050642N1**
Registration date: **2021-03-30, 1400/01/10**
Registration timing: **prospective**

Last update: **2021-03-30, 1400/01/10**
Update count: **0**

Registration date
2021-03-30, 1400/01/10

Registrant information

Name
Seyed Kamran Sajadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 0000 0000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2021-10-12, 1400/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of prolotherapy in perineural points and lower extremity acupoints on neuropathic pain in patients with neuropathy

Public title
The effect of prolotherapy injection in the treatment of neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical signs of lower limb neuropathy in the last three months No response to conventional treatments Age 30-60 years Complete and sign the consent form
Exclusion criteria:
any tumor, infection, or skin lesion at the target site Pregnancy Bleeding disorders History of allergies to the drugs used
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: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
The total number of eligible patients is 48. This number is randomly divided by computer into three groups: perineural, acupuncture and control, each group of 16 people. Random allocation is done with 6 blocks.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is performed in double blind method. The type and volume of drug injected and its appearance are the same in all groups. Patients do not know the injection site in other groups. Also, the data analyzer is not aware of the interventions made in the groups.
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
Street address
Ethics Committee in Medical Research, Vice Chancellor for Research, 7th Floor, Central Building of Shiraz University of Medical Science, Zand St., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2019-09-16, 1398/06/25
Ethics committee reference number
IR.SUMS.MED.REC.1398.402

Health conditions studied

1

Description of health condition studied
Neuropathy
ICD-10 code
G62.9
ICD-10 code description
Polyneuropathy, unspecified

Primary outcomes

1

Description
Douleur Neuropathique 4 questionnaire (DN4) score
Timepoint
For all patients, Douleur Neuropathique 4 questionnaire is filled out before injection and then in the first, second and eighth weeks after injection
Method of measurement
Completion of Douleur Neuropathique 4 Questionnaire

2

Description
Overall Neuropathy Limitations Scale (ONLS) score
Timepoint
For all patients, Overall Neuropathy Limitations Scale (ONLS) is filled out before injection and then in the first, second and eighth weeks after injection
Method of measurement
Completion of Overall Neuropathy Limitations Scale (ONLS) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: after sterilizing the injection site with betadine, injection of 5 cc of 5% dextrose solution construction of Pasteur Institute with 1 cc of 2% lidocaine solution construction of Pasteur Institute around 3 peripheral nerves, tibial sural and saphenous, in the ankle area based on anatomical landmarks, 2 cc each point, subcutaneous with an angle of 45 degrees and a depth of 4 mm, with needle gage 25. Weekly injections for 3 consecutive weeks, number of patients in this group is 16. Oral pregabalin 75 mg twice daily for all patients

Category

Rehabilitation

2

Description

Intervention group 2: after sterilizing the injection site with betadine, injection of 5 cc of 5% dextrose solution construction of Pasteur Institute with 1 cc of 2% lidocaine solution construction of Pasteur Institute around 3 foot acupuncture points, ST41, ST44 and GB40 points, 2 cc each point, subcutaneous with an angle of 45 degrees and a depth of 4 mm, with needle gage 25. Weekly injections for 3 consecutive weeks, number of patients in this group is 16. Oral pregabalin 75 mg twice daily for all patients

Category

Rehabilitation

3

Description

Control group: oral pregabalin 75 mg twice daily, without injection in the foot. Number of patients in this group is 16

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza specialized and sub-specialized clinic

Full name of responsible person

Sharareh Roshanzamir

Street address

Imam Reza specialized and sub-specialized clinic, Namazi Square, Shiraz, Iran

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2

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Sharareh Roshanzamir

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Faghihi hospital, Zand st., Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi, Vice Chancellor for Research, Shiraz University of Medical Sciences

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Vice Chancellor for Research and Technology, Seventh Floor, Central Building of Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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7134814336

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vcrdep@sums.ac.ir

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
Shiraz University of Medical Sciences
Full name of responsible person
Sharareh Roshanzamir
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data in this study will be shared without mentioning patients' identities, including patient grouping, injection methods, data obtained, and data analysis methods.
When the data will become available and for how long
Data will be available 3 months after approval
To whom data/document is available
The data will be accessible to physician colleagues in all disciplines as well as to patients
Under which criteria data/document could be used
Access to the data in this study will not require special conditions
From where data/document is obtainable
sharareh.roshanzamir@gmail.com
What processes are involved for a request to access data/document
An email request is sufficient
Comments