Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of mesotherapy using drugs versus transcutaneous electrical nerve stimulation (tens) lumbosacral chronic radiculopathy due to disk herniation

Protocol summary

Study aim

Determining and comparing the therapeutic effect of mesotherapy and TENS in improving pain and function in patients with chronic radicular back pain.

Design

A parallel randomized clinical trial study in 1402-1403 on 60 patients diagnosed with chronic radiculopathy due to disc, who were randomly assigned to one of the two intervention groups.

Settings and conduct

In this one-sided blind study, patients with chronic lumbar radiculopathy referred to physical medicine clinics of Isfahan University of Medical Sciences in 1402-1403 were randomly treated with mesotherapy and TENS, and after the completion of sampling and flow-up analysis of the data by the individual It is done without the knowledge of the groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with chronic radicular back pain due to disc herniation, age over 18 years, moderate and severe pain exclusion criteria: surgery or mesotherapy in the last 3 months, severe rheumatological and systemic or neurological diseases, inflammation in the sacroiliac joint, fracture in spine, spondylolysis or spondylolisthesis, Coagulation disorder, cancer, metabolic bone diseases, anatomical abnormalities of the spine, allergy to the drugs used, kidney failure, skin disease at the injection site. Use of complementary treatments 1 month before treatment or during treatment, drug addiction

Intervention groups

first intervention group: 6 sessions of subcutaneous mesotherapy injection of acupuncture points for back pain with the combination of 1 ml of piroxicam. 1ml of 2% lidocaine , second intervention group, transcutaneous electrical nerve stimulation (TENS)used for 10 sessions with one day intervals of 100 Hz electric current with 4 electrodes on 8 x 4 rubber for 20 minutes, all patients 10 mg Baclofen and Williams exercises 3 times a day and 5 sets each time.

Main outcome variables

pain ,function

General information

Reason for update

Acronym

transcutaneous electrical nerve stimulation (tens)

IRCT registration information

IRCT registration number: **IRCT20231203060255N1**
Registration date: **2024-04-09, 1403/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-09, 1403/01/21**
Update count: **0**

Registration date

2024-04-09, 1403/01/21

Registrant information

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Fateme Hoseinzade
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-15, 1402/07/23

Expected recruitment end date

2024-05-12, 1403/02/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of mesotherapy using drugs versus transcutaneous electrical nerve stimulation (tens) lumbosacral chronic radiculopathy due to disk herniation

Public title

efficacy of mesotherapy in the treatment of chronic radiculopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1-Consent to participate in the study2- Patients with chronic radicular back pain due to a herniated disc (radicular pain for more than three months and confirming the diagnosis of a herniated disc as the cause of the symptoms by MRI and matching the patient's radicular symptoms with a herniated disc observed in the MRI according to the diagnosis of a physical medicine specialist3- Age above 18 years4- moderate and severe pain intensity (above 5 based on VAS)

Exclusion criteria:

1- Surgery in the last 3 months2- Rheumatological diseases or severe systemic diseases (diabetes,...)3- Neurological diseases (MS, neuropathy,...)4- History of mesotherapy in the last 3 months5- The presence of inflammation in the sacroiliac joint during examinations6- history of fracture in the spine7 presence of spondylolysis or spondylolisthesis8- Coagulation disorders (genetic disorders such as hemophilia or acquired disorders such as warfarin use)9- History of any type of cancer 10- Bone metabolic diseases such as Paget11- Anatomical abnormalities of the spine such as scoliosis12- History of any allergy to the drugs used (allergy to lidocaine or NSAID)13-Kidney failure14- Skin disease at the injection site15- Use of complementary treatments including acupuncture and herbal medicines 1 month before treatment or during treatment16-Drug addiction

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

How to select the sample: random sampling is done by consecutive non-probability sampling, and the number of samples is based on the calculation formula and the number of 30 people in each group, a total of 60 people (n=30). and random allocation ,the samples included in the study are allocated to 2 groups using SPSS software. In this way, 30 random numbers from 1 to 60 are created by Excel software, which are assigned to the first intervention group, and then the remaining 30 numbers are assigned to the second group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4, Research and Technology Vice-Chancellor

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Province

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8174673461

Approval date

2023-10-15, 1402/07/23

Ethics committee reference number

IR.MUI.MED.REC.1402.263

Health conditions studied

1

Description of health condition studied

chronic radiculopathy

ICD-10 code

M54.17

ICD-10 code description

Radiculopathy, lumbosacral region

Primary outcomes

1

Description

pain

Timepoint

Immediately after treatment, one month after treatment, two months after treatment

Method of measurement

Visual Analogue Scale

2

Description

Patient function

Timepoint

Immediately after treatment, one month after treatment, two months after treatment

Method of measurement

RMQ (Roland Morris Disability Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:2 sessions per week for 3 weeks of mesotherapy for a total of 6 sessions of subcutaneous mesotherapy in acupuncture points related to back pain with 1 ml of piroxicam and 2 ml of 2% lidocaine along with exercise and muscle relaxant.

Category

Treatment - Other

2

Description

Intervention group: Intervention group: Transcutaneous electrical nerve stimulation (TENS) treatment is used with a protocol of 10 sessions with one-day intervals, in which 100 Hz electric current with 4 8x4 rubber electrodes is used for 20 minutes in each session

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Parisa Taheri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

parisa taheri

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

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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