

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Name

Fateme Hoseinzade

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3233 0973

##### Email address

fatemehoseinzade@gmail.com

##### 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

**City**

isfahan

**Province**

Isfahan

**Postal code**

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

**Street address**

Shahada Square - Ibn Sina St. - Sanbulistan St. - Amin Medical Education Cente

**City**

isfahan

**Province**

Isfahan

**Postal code**

8148653141

**Phone**

+98 31 3112 2020

**Email**

Prs\_taheri@yahoo.com

**Web page address**

https://amin.mui.ac.ir/

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholamreza Asgari

**Street address**

Building No. 4,Hazar Jarib Street,Isfahan University of Medical Sciences

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

askari@mui.ac.ir

**Web page address**

https://research.mui.ac.ir/fa

**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**

Physical Medicine

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

Prs\_taheri@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

fateme hoseinzade

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

fatemehoseinzade98@gamil.com

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

fateme hoseinzade

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Hazar Jarib St., Isfahan University of Medical Sciences

**City**

isfahan

**Province**

Isfahan

**Postal code**

91746734461

**Phone**

+98 31 3668 0048

**Email**

fatemehoseinzade98@gmail.com

**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