Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Studying the effect of adding traction therapy to conventional physical modalities in the treatment of lumbar radiculopathy

Protocol summary

Study aim
Investigating the effect of adding teletherapy to conventional physiotherapy treatments on improving pain, reducing functional disability, and increasing active range of motion in patients with lumbar radiculopathy

Design
A controlled, double-blind, randomized, phase 3 clinical trial with a parallel group on 50 patients, randomized using a randomized permutation block design.

Settings and conduct
The study is conducted at the Mobasher Physical Medicine and Rehabilitation Clinic of Hamadan University of Medical Sciences. Individuals with lumbar radiculopathy, after meeting the conditions and inclusion and exclusion criteria of the study, are invited to voluntarily participate in the research project. After consenting to participate in the study, the personal characteristics form and inclusion and exclusion criteria and demographic questionnaire including age, gender, occupation, symptoms, clinical examinations, and medical history of the individual are completed by the examiner and divided into two experimental and control groups using randomized permutation blocks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with unilateral lumbar radiculopathy based on clinical examination and MRI_Onset of symptoms more than one month before study entry. Exclusion criteria: Active spinal fracture_ History of previous spinal surgery

Intervention groups
Intervention group: Routine physiotherapy treatment (TENS + McKenzie and stabilizing exercises) + teletherapy (Tecar 560G device, 10 sessions, 20 minutes per session including 10 minutes of capacitance at 600 kHz and 10 minutes of resistance at 450 kHz) Control group: Only routine physiotherapy treatment similar to the intervention group, without teletherapy

Main outcome variables
Severity of low back and lower limb pain_Low back disability index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241211064021N13**
Registration date: **2025-12-23, 1404/10/02**
Registration timing: **prospective**

Last update: **2025-12-23, 1404/10/02**
Update count: **0**

Registration date
2025-12-23, 1404/10/02

Registrant information

Name
Faeze Noori

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3131 4033

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ethics@umsha.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-01-21, 1404/11/01

Expected recruitment end date
2027-01-21, 1405/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Studying the effect of adding traction therapy to conventional physical modalities in the treatment of lumbar radiculopathy

Public title
Investigating the effect of adding chiropractic to conventional physical modalities in the treatment of lumbar radiculopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with unilateral lumbar radiculopathy based on clinical examination and MRI Age between 20 and 50 years Written informed consent to participate in the study Onset of symptoms more than one month before study entry

Exclusion criteria:
Active spinal fracture History of previous spinal surgery

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method will be used to implement random assignment. In this way, 30 consecutive numbers (from 1 to 30) will be written separately on paper and placed in a container. Then, each participant in the experiment will be asked to randomly select one of these 50 numbers from the container containing the numbers. People who chose numbers 1 to 25 will be assigned to group A ("Intervention Group 1"), people who chose numbers 26 to 50 will be assigned to group B ("Intervention Group 2").

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is conducted in a double-blind manner. To reduce bias in the study, the main researcher as the evaluator will not divide the samples into two groups, so he will not be aware of the grouping of the individuals, and the grouping of the samples and the intervention will be done by the physiotherapist, and the information obtained from the data will be provided to the statistical evaluator in a coded and non-identifiable form. Therefore, this study is a double-blind type.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences

Street address
Shahid Fahmideh St

City
Hamadan

Province
Hamadan

Postal code
6517838678

Approval date
2025-10-25, 1404/08/03

Ethics committee reference number
IR.UMSHA.REC.1404.656

Health conditions studied

1

Description of health condition studied
Studying the effect of adding traction therapy to conventional physical modalities in the treatment of lumbar radiculopathy

ICD-10 code
M54.16

ICD-10 code description
Radiculopathy, lumbar region

Primary outcomes

1

Description
Severity of back and lower limb pain

Timepoint
At the beginning of the study (Baseline) _ After the tenth treatment session (End of treatment) _ Three months after the end of treatment (Follow-up)

Method of measurement
With a numerical pain rating scale (NRS or Numeric Rating Scale: 0–10); the patient reports the intensity of pain at rest and during activity.

Secondary outcomes

1

Description
Lumbar Disability Index
Timepoint
At the beginning of the study, at the end of the tenth session, and three months after the end of treatment
Method of measurement
Valid Persian version of the ODI questionnaire (10 questions, score 0–50; converted to percentage of disability)

Intervention groups

1

Description
Intervention group: Técar Therapy + conventional physiotherapy. In addition to receiving a standard conventional physiotherapy program (including specific exercises), patients in this group will receive one Técar Therapy session at a specified time interval (e.g., five times a week for two weeks).
Category
Rehabilitation

2

Description
Control group: Usual Physiotherapy. Description: Patients in this group only received the standard usual physiotherapy program prescribed for the treatment of lumbar radiculopathy. The usual physiotherapy treatment included 10 sessions of TENS plus exercise therapy, which was used in no particular order in each treatment session for 35 minutes (20 minutes of low-frequency TENS, with a frequency of 5 Hz and a pulse duration of 300 microseconds and the use of IR for 15 minutes on the lumbar region), exercise therapy including McKenzie exercises and lumbopelvic stabilization exercises (bridge, quadrupeds, and cross-leg raises).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobasher Kashani Physical Medicine and Rehabilitation Clinic, Hamadan University of Medical Sciences
Full name of responsible person
Saideh Kakavand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
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assistant
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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
A large portion of the data is potentially shareable.
When the data will become available and for how long
Access to data will be available immediately after the final article is published.
To whom data/document is available
All researchers, researchers and clinical experts will be allowed to access the data of this study.
Under which criteria data/document could be used
It will be welcomed to conduct extensive analysis on the data of this study along with the data of other studies to write meta-analysis review articles.
From where data/document is obtainable
For more information, please send an email to Dr. Saeideh Kakavand. All correspondence will be sent to the email address entifad@gmail.com.
What processes are involved for a request to access data/document
After making a phone call and submitting a request via email, a final response will be sent within at least 1 month.
Comments