

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Evaluation of adding tecar therapy effect on routine physiotherapy treatments compared to placebo tecar and routine physiotherapy treatments on pain, disability and electrical activity of erector spine muscles in patients with non-specific chronic low back pain

Protocol summary

Study aim

The evaluation of adding tecar therapy effect on routine physiotherapy treatments compared to placebo tecar and routine physiotherapy treatments on pain, disability and electrical activity of erector spine muscles in patients with non-specific chronic low back pain

Design

Clinical trial with a control group, with parallel groups, three blinded, randomized, on 32 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this study, 32 patients with non-specific chronic back pain are divided into two groups of 16, treatment and control. In the treatment group, 20 minutes of Tecar therapy, 35 minutes of routine physiotherapy (20 minutes of TENS and 15 minutes of IR and exercise therapy) and the control group (placebo Tecar and routine physiotherapy) are performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with back pain who do not have documentation of discopathy or disc herniation Patients with symptoms of chronic back pain who are between 20 and 60 years old Diagnosis of chronic back pain for at least 12 weeks Visual pain index 4-7 Exclusion criteria: Contraindication of tecar therapy: neoplasm, regional infection, patients with cardiac pacemaker and pregnancy. Active vertebral fracture previous spine surgery Rheumatoid diseases such as rheumatoid arthritis infectious diseases Systemic diseases that affect pain perception, such as diabetes and... Local injection such as (local anesthesia, corticosteroid...) Taking medicines and doing physiotherapy in the last 4 weeks

Intervention groups

The intervention group includes Tecar therapy, routine physiotherapy (IR, TENS and exercise therapy). The control group is the same as the intervention group, but

Tecar will be done as placebo.

Main outcome variables

VAS scale Oswestry disability scale electrical activity of the paraspinal muscles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056358N1**

Registration date: **2022-11-21, 1401/08/30**

Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**

Update count: **0**

Registration date

2022-11-21, 1401/08/30

Registrant information

Name

Morteza Heydarinasir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3311 7923

Email address

m.heydarinasir@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of adding tecar therapy effect on routine physiotherapy treatments compared to placebo tecar and routine physiotherapy treatments on pain, disability and electrical activity of erector spine muscles in patients with non-specific chronic low back pain

Public title

The Evaluation of adding tecar therapy effect on routine physiotherapy treatments compared to placebo tecar and routine physiotherapy treatments on pain, disability and electrical activity of erector spine muscles in patients with non-specific chronic low back pain

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with symptoms of chronic back pain who are between 20 and 60 years old
Diagnosis of chronic back pain for at least 12 weeks
Visual pain index 4-7
Patients with back pain who have no documentation of discopathy or disc herniation

Exclusion criteria:

Contraindication of tecar therapy: neoplasm, regional infection, patients with cardiac pacemaker and pregnancy. Active vertebral fracture previous spine surgery
Rheumatoid diseases such as rheumatoid arthritis
infectious diseases
Systemic diseases that affect pain perception, such as diabetes and...
Local injection such as (local anesthesia, corticosteroid...) Taking medicines and doing physiotherapy in the last 4 weeks

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this research is done in the form of simple sampling. Allocation of samples (into two groups) is done randomly using the Stratified Permuted Block Randomization method with 5 blocks of 4 and 8 assigned to two groups
1 BBBAABAA
2 ABAB
3 AABBAABB
4 AABBBABA
5 AABB. Considering A as the

routine physiotherapy treatment group and B as the exercise group, the methodologist randomly selects a number between 1 and 5 after each patient enters. The result of the lottery result of the corresponding block number is determined. In the next step, by referring to the above table, the type of intervention (whether it is A or B) is determined. For example, let's assume that the number 3 appears at some point in the lottery, by referring to block three, we can see that before AAB choices were made and now it is the turn to perform intervention B, then, the expert is asked for this patient exercise and Takar should be done together. In the image that the block number appeared in the lottery that all the previous options were completed, the lottery is completed again until the number of duplicate samples is completed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The main researcher will not divide the samples into two groups, and this work will be done by the research assistant who is a physiotherapy expert, and the information obtained from the data will be provided to the statistical evaluator in a coded and non-recognizable form. And the evaluator will not know about the grouping of people. Also, the intervention is done by another person, and the evaluation before and after the treatment is done by the main researcher, so this study is a thriple-blind one.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

East Sahib Al Zaman Street, corner of Pakan Alley, P7

City

asadabad

Province

Hamadan

Postal code

6541833586

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.SEMUMS.REC.1401.190

Health conditions studied

1

Description of health condition studied

non-specific chronic low back pain

ICD-10 code

M95-M99

ICD-10 code description

Other disorders of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

pain

Timepoint

Before the intervention and two weeks after the intervention and 1 month after the end of the last session of the intervention.

Method of measurement

visual analogue scale- -

2

Description

Functional disability

Timepoint

Before the intervention and two weeks after the intervention and 1 month after the end of the last session of the intervention.

Method of measurement

Oswestry disability scale

3

Description

Electrical activity of erector spine muscles

Timepoint

Before the intervention and two weeks after the intervention and 1 month after the end of the last session of the intervention.

Method of measurement

Electromyographic device

Secondary outcomes

empty

Intervention groups

1

Description

The patients in the treatment group are treated for 5 sessions a week and a total of 10 sessions. 10 minutes of capacitive Tecar and 10 minutes of resistance Tecar are used. The frequency of the capacitive phase of the treatment is 600 KHZ and the frequency of the resistive phase of the treatment is 450 KHZ. Intensity in both

types of treatment is 10-12 w or 0.42 j/cm² for an area of 228.2 cm. The routine physiotherapy treatment is 10 sessions of TENS along with therapeutic exercises similar to the sessions of the treatment group and in each treatment session for 35 minutes (20 minutes 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 lower back area), therapeutic exercise including lumbar pelvic stabilization exercises and paraspinal stretching

Category

Rehabilitation

2

Description

Control group: Routine physiotherapy treatment, 10 sessions of TENS along with therapeutic exercises similar to the sessions of the treatment group and in each treatment session for 35 minutes (20 minutes of low frequency TENS, with a frequency of 5 Hz and pulse duration of 300 microseconds and use of IR for 15 minutes on the lower back area), therapeutic exercises include lumbar pelvic stabilization exercises and paraspinal stretching. Also, Tecar placebo is used.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic, Faculty of Rehabilitation, Hamadan University of Medical Sciences

Full name of responsible person

Morteza Heydari Nasir

Street address

East Sahib Al Zaman St. corner of Pakan Alley

City

Asadabad

Province

Hamadan

Postal code

6541833586

Phone

+98 81 3311 7923

Fax

+98 81 3311 7923

Email

m.heydarinasir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mir Mohammad Khani

Street address

East Sahib Al Zaman St. corner of Pakan Alley

City

Asadabad

Province

Hamadan

Postal code

6541833586

Phone

+98 81 3311 7923

Fax

+98 81 3311 7923

Email

m.heydarinasir@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

1

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**

Semnan University of Medical Sciences

Full name of responsible person

Morteza Heydari Nasir

Position

Master science student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

East Sahib Al Zaman St. corner of Pakan Alley

City

Asadabad

Province

Hamadan

Postal code

6541833586

Phone

+98 81 3311 7923

Fax

+98 81 3311 7923

Email

m.heydarinasir@gmail.com

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

Semnan University of Medical Sciences

Full name of responsible person

Morteza Heydari Nasir

Position

Master science student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

East Sahib Al Zaman St. corner of Pakan Alley

City

Asadabad

Province

Hamadan

Postal code

6541833586

Phone

+98 81 3311 7923

Email

m.heydarinasir@gmail.com

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

Semnan University of Medical Sciences

Full name of responsible person

Morteza Heydari Nasir

Position

Master science student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

East Sahib Al Zaman St. corner of Pakan Alley

City

Asadabad

Province

Hamadan

Postal code

6541833586

Phone

+98 81 3311 7923

Email

m.heydarinasir@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

No - There is not 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

Not applicable

Data Dictionary

Not applicable