Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 (placeboTecar 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

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Iran (Islamic Republic of)

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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

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

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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
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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
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
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Morteza Heydari Nasir
Position
Master science student
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Person responsible for updating data

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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

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