Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

Protocol summary

Study aim

The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

Design

The sampling method in this study is of an unpredictable type available in the form of easy sampling from people who are available in the community to the examiner. The method of grouping is randomized to one person, in which, after the initial examination, using Excel software, the subjects are in one of two groups of 1 or 2; group 1, the group under the usual treatment of physiotherapy In group 2, the group is under treatment with regular treatment with physiotherapy.

Settings and conduct

First, volunteers are checked for entry and exit criteria. Then, in order to observe ethical points of view, the objectives, methodology and conditions of the test will be fully explained to eligible individuals. If people are willing to participate in the study, informed consent is obtained from the project. Prior to conducting the main study, a preliminary study is conducted to examine the relative and absolute repeatability of the information collected by a test. To measure dependent variables such as pain intensity, range of motion, functional disability, all conditions are quite similar to The main study will be done. In order to measure the severity of pain, the VAS index is used for assessing functional disability. The Oswestry and Roland-Mauritius questionnaires are not used. Repeatability is not required. Inclinometer meter is used to measure the range of motion. In order to verify its repeatability, the amplitude Flexion, extension and side bending 8 to 10 subjects are first examined during the initial examination, and the second time, 15 to 20 minutes after the examination and before the treatment, and the correlation between the numbers obtained for each We will examine the person.

Participants/Inclusion and exclusion criteria

Entry requirements: women and men between 20 and 60 years, history of back pain for more than 3 months, or at least half a day in the last 6 months, pain intensity greater than 3 based on VAS index, no acute and inflammatory back pain, subacute and tracheostomy back pain Lack of spinal cord stenosis, scoliosis and ankylosing spondylitis, lack of postpartum back pain or pregnancy, no history of bone surgery, fractures of the lower back, osteoporosis, infection, cancer, neurological diseases, etc., having no history of any treatment Physiotherapy for the waist during the past month Exit criteria: The use of medication during the study, the unwillingness of the participant to continue the treatment, have been trained in exercises other than those during the course of the treatment.

Intervention groups

Participants are grouped randomly in two different therapeutic groups, a group treated with TECAR and a group treated with usual Physical Therapy.

Main outcome variables

severity of pain, functional disability, range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171224038043N1**
Registration date: **2018-01-24, 1396/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-24, 1396/11/04**
Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

Mozhdeh Dariush

Name of organization / entity

Country
Iran (Islamic Republic of)
Phone
+98 21 7750 6157
Email address
mo.dariush@uswr.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-13, 1396/10/23
Expected recruitment end date
2018-08-22, 1397/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain

Public title
The Effect of TECAR Therapy on Pain Relief, Functional Disability and Range of Motion in Patients with Non-specific Chronic Low Back Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women between the ages of 20 and 60 History of back pain for more than 3 months, or at least half a day in the last 6 months Pain intensity greater than 3 according to V.A.S Not having acute and inflammatory back pain, subacute and traumatic low back pain Not having spinal canal stenosis, scoliosis and ankylosing spondylitis Not having back pain after delivery or during pregnancy Not having history of bone surgery, lumbar vertebral fracture, osteoporosis, infection, cancer, neurological diseases Not having a history of any type of physical therapy for your back during the past month
Exclusion criteria:
Use of medication during research Participant's reluctance to continue treatment Doing exercises other than those trained in the course of treatment
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized
Randomization description
Randomize Using Excel
Blinding (investigator's opinion)
Double blinded
Blinding description
Individuals in each group are unaware of the existence of the other group, and those who do the treatment are not grouped and the participants in each group are unaware.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the University of Social Welfare and Rehabilitation Sciences
Street address
Kodakyar Ave., Daneshjo Blvd., Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Approval date
2018-01-06, 1396/10/16
Ethics committee reference number
IR.USWR.REC.1396.282

Health conditions studied

1

Description of health condition studied
Non-specific chronic low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain severity score with the V.A.S index
Timepoint
The beginning and the end of each treatment session and one week after the completion of the study
Method of measurement

V.A.S index

2

Description
Functional disability assessment through Oswesterry and Roland-morris questionnaires
Timepoint
The beginning and the end of each treatment session and one week after the completion of the study
Method of measurement
Oswestry and Roland-morris questionnaires score

3

Description
Measuring the range of motion through the Inclinometer tilt
Timepoint
The beginning and the end of each treatment session and one week after the completion of the study
Method of measurement
Inclinometer Tilometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A treatment group with TECAR, 10 sessions of treatment with a TECAR machine, along with the usual treatment of physiotherapy that is exactly the same as the control group.The sessions were every other day .
Category
Treatment - Devices

2

Description
Control group: The usual physical therapy therapy group, 10 sessions of TENS with exercise sessions were one day and each treatment session was 30 minutes TENS (15 minutes of high frequency or TENS normal at 100 Hz and 40 microsecond pulse duration, And 15 min low frequency TENS, with a frequency of 5 Hz and a pulse duration of 300 microseconds, without special order)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Novin Teb Physiotherapy
Full name of responsible person
Mozhdeh Dariush
Street address
First Floor ,No. 416, Abureyhan Station, Between 30 Meters Narmak and Khaghani, Damavand Avenue
City
Tehran
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1743795149
Phone
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Email
mozhdeh_dariush@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Iraj Abdollahi
Street address
Dead end Koodakyar, Daneshjo Boulevard, Daneshgah Square
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۱۹۸۵۷۱۳۸۳۴
Phone
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ir.abdollahi@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Novin Teb Physiotherapy
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mozhdeh Dariush

Position
student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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mozhdeh_dariush@yahoo.com

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The total potential data is shared after being unidentified
When the data will become available and for how long
Start the access period, 5 months after printing the results
To whom data/document is available
Researchers and experts in this field
Under which criteria data/document could be used
In order to complete the information of the researcher and carry out statistical analyzes and provide documentation on the conduct of the research approved and under the supervision of professors of the university
From where data/document is obtainable
By email (mozhdeh_dariush@yahoo.com), phone call (09127965250)
What processes are involved for a request to access data/document
Submission of documentation for the research to be approved and under the supervision of university professors
Comments