Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Effects of one session interferential therapy on electroencephalography of patients with chronic nonspecific low back pain: A Randomized Controlled Trial

Protocol summary

Study aim
Effects of one session interferential therapy on electroencephalography of patients with chronic nonspecific low back pain

Design
Clinical trial with control and placebo groups and intervention, with parallel groups, double-blind, randomized with Random software allocation, number of patients 20 and healthy individuals 20

Settings and conduct
This study will be performed in the Tabriz University of Medical Sciences. All participants will have an EEG recorded before and after the intervention and pain intensity of low back pain patients will be recorded before and after the intervention. Blinding will be done by keeping participants and data analyzers unaware of groupings

Participants/Inclusion and exclusion criteria
Inclusion criteria for low back pain patients are having a minimum pain intensity of 4 on the VAS scale for more than 3 months in the lower back with or without radiating to the lower extremities. Healthy people should also not report any chronic pain. Exclusion criteria for patients are disorders such as fractures, tumors, discopathy that indicate the specificity of low back pain, having concomitant treatment, treatment with corticosteroids in the past 2 weeks and physiotherapy in the past 8 weeks. Other exclusion criteria for patients and healthy individuals include: Cancer patients and people with pacemakers, People with electrotherapy contraindications, People with sleep disorders, or taking drugs that affect the nervous system, or History People with neurological and psychological disorders, who have metal implants in their spine, pregnant women

Intervention groups
Intervention: interferential current with effective intensity- low back pain patients Placebo: interferential current with ineffective intensity- low back pain patients Control: interferential current with effective intensity- healthy people

Main outcome variables
Intensity of pain, power of brain waves

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210316050727N1**
Registration date: **2021-07-06, 1400/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-06, 1400/04/15**
Update count: **0**

Registration date
2021-07-06, 1400/04/15

Registrant information

Name
Abas Soltani someh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3337 5359

Email address
ab.soltani@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2021-09-06, 1400/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of one session interferential therapy on electroencephalography of patients with chronic nonspecific low back pain: A Randomized Controlled Trial

Public title
Effects of interferential therapy on electroencephalography of patients with chronic nonspecific low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Low back pain with or without pain radiating to the lower extremities above the knee for more than three months Pain perception over 40 mm in the Visual Analogue Scale
Exclusion criteria:
Existence of any serious disorders in the spine such as fractures, tumors, inflammatory diseases Nerve root disorders confirmed by neurological testing Having simultaneous treatment Cancer patients and heart patients with pacemakers Any contraindicationto the use of electrotherapy Having received physiotherapy treatment in the eight weeks before data collection Having metal implants in the spine Pregnancy Taking drugs that affect the nervous system History of neuropsychological diseases Corticosteroid treatment in the last 2 weeks sleep disorder
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, Random software allocation For the allocation concealment, the type of intervention received is written on a piece of paper and placed inside the opaque envelopes and the back of the envelope will be numbered. The envelopes will be opened according to the entry of the participants and the type of group for each patient will be specified accordingly.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants: Individuals are unaware of the groupings and the group to which they belong and there is no exchange of information between participants. Data Analyzer: The collected information is provided to the analyzer without mentioning the groupings and patient information.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Rehabilitation faculty, Daneshgah avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Approval date
2021-02-14, 1399/11/26
Ethics committee reference number
IR. TBZMED.REC.1399.1036

Health conditions studied

1

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

Primary outcomes

1

Description
Theta wave power(Absolute power of the frequency range 4-7 Hz)
Timepoint
Before and after the intervention
Method of measurement
EEG recorder

2

Description
Alpha wave power(Absolute power of the frequency

range 8-12 Hz)

Timepoint

Before and after the intervention

Method of measurement

EEG recorder

3

Description

Beta wave power(Absolute power of the frequency range 13-30 Hz)

Timepoint

Before and after the intervention

Method of measurement

Absolute power of the frequency range 13-30 Hz

4

Description

Gamma wave power(Absolute power of frequency range above 30 Hz)

Timepoint

Before and after the intervention

Method of measurement

EEG recorder

5

Description

Intensity of pain(VAS scale score)

Timepoint

Before and after the intervention

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the intervention group, participants will receive one session interferential current for 30 minutes with a carrying frequency of 4 kHz and a bit frequency of 100 Hz with intensity at the level of sensory stimulation in the lumbar region. The intensity of the current increases until the patient has a strong tingling sensation and at the same time comfort, and the intensity of the current will increase every 5 minutes.

Category

Treatment - Other

2

Description

Intervention group 2: placebo group, In the placebo group, patients will receive one session interferential current for 30 minutes with a carrying frequency of 4 kHz and a bit frequency of 100 Hz with ineffective intensity so that the current intensity does not reach the target point and every 5 minutes without increasing the current intensity, the patient's comfort will be questioned.

Category

Placebo

3

Description

Control group: Healthy people participating in the study will receive one session interferential current for 30 minutes with a carrying frequency of 4 kHz and a bit frequency of 100 Hz with intensity at the level of sensory stimulation in the lumbar region. The intensity of the current increases until the patient has a strong tingling sensation and at the same time comfort, and the intensity of the current will increase every 5 minutes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic, Rehabilitation Faculty, Tabriz University of Medical Sciences

Full name of responsible person

Abas soltani someh

Street address

Faculty of rehabilitation, Golgasht Ave, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3326 3293

Email

ab.soltani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad samiei

Street address

Vice-Chancellor for Research and Technology, Daneshgah avenue, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 7310

Email
Samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Abas Soltani someh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Rehabilitation Faculty, Daneshgah avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3337 5359
Fax
+98 41 3337 5359
Email
ab.soltani@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abas Soltani someh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Rehabilitation Faculty, Daneshgah avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3337 5359
Fax
+98 41 3337 5359
Email
ab.soltani@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abas Soltani someh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Rehabilitation Faculty, Daneshgah avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5167631444
Phone
+98 41 3337 5359
Fax
+98 41 3337 5359
Email
ab.soltani@yahoo.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
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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document

Study protocol, statistical analysis plan,and informed consent form will be available to share with other investigators if they request by email.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions in Iran

Under which criteria data/document could be used

In case of journal or reviewers request for data set

From where data/document is obtainable

Via email and giving documents to prove their identity for administrator Dr Abas Soltani ab.soltani@yahoo.com

What processes are involved for a request to access data/document

Sending email and documents to prove their identity

Comments