Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Does The Application of Interferential Current Therapy with Vacuum Electrodes Provide Additional Effect in Patients with Nonspecific Chronic Low Back Pain? A Randomized Controlled Study

Protocol summary

Study aim

To evaluate effectiveness of interferential current therapy (IFT) on pain, disability and quality of life in patients with chronic low back pain and to compare the advantages of application IFT with vacuum and carbon silicon pad electrodes to each other.

Design

This is a single blinded randomized controlled trial. Randomization was made by sealed numbered envelopes. The same physician blinded to randomization evaluated all the patients before treatment, and on the first and twelfth week after the end of the treatments. Patients were not blinded.

Settings and conduct

There were three groups in this study. Patients were evaluated three times: before treatment, one week and twelve weeks after treatment with the same investigator whom was blinded for the group allocation. Assessor was blinded (by sealed envelopes method), patients were not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: to be more than 18 years old; seeking treatment for chronic low back pain. Exclusion criteria: cognitive dysfunction; neurological deficits; an extruded and/or sequestrated lumbar disc herniation; spinal fusion; pregnancy; malignancy; spinal compression fracture; spondylolisthesis; severe peripheral neuropathy; an aortic aneurysm; vertebral infection; rheumatological disease; vertebral column surgery.

Intervention groups

One hundred patients with LBP were randomized in three groups. Group-1 received interferantial current therapy with vacuum electrodes, Group-2 received interferantial current therapy with carbon silicon pad electrodes. Group-3; received no interferantial current therapy. All of the groups have performed core stabilizating exercises.

Main outcome variables

Pain was assessed using Visual Analog Scale, disability with Oswestry Disability Index and quality of life with Short Form-36.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038268N3**
Registration date: **2018-04-13, 1397/01/24**
Registration timing: **retrospective**

Last update: **2018-04-13, 1397/01/24**
Update count: **0**

Registration date

2018-04-13, 1397/01/24

Registrant information

Name

Fatmanur Aybala Koçak

Name of organization / entity

Ahi Evran University Faculty of Medicine

Country

Turkey

Phone

+90 386 213 45 15

Email address

aybala.kocak@ahievran.edu.tr

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-02-01, 1393/11/12

Expected recruitment end date

2017-02-01, 1395/11/13

Actual recruitment start date

2015-03-01, 1393/12/10

Actual recruitment end date

2017-03-01, 1395/12/11

Trial completion date

empty

Scientific title

Does The Application of Interferential Current Therapy with Vacuum Electrodes Provide Additional Effect in Patients with Nonspecific Chronic Low Back Pain? A Randomized Controlled Study

Public title

Does The Application of Interferential Current Therapy with Vacuum Electrodes Provide Additional Effect in Patients with Nonspecific Chronic Low Back Pain? A Randomized Controlled Study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

To be more than 18 years old Seeking treatment for chronic low back pain

Exclusion criteria:

cognitive dysfunction neurological deficits an extruded and/or sequestrated lumbar disc herniation spinal fusion pregnancy malignancy spinal compression fracture spondylolisthesis severe peripheral neuropathy an aortic aneurysm vertebral infection rheumatological disease vertebral column surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Casual randomization using sealed numbered envelopes without strata or blocks was performed by an administrative assistant. The same physician blinded to randomization evaluated all the patients before treatment, and on the first and twelfth week after the end of the treatments. After evaluation by the physiatrist the patients were randomized into three groups: Group 1: The patients in this group were applied interferential current with vacuum electrodes (n = 34) and exercise therapy. Group 2: The patients in this group were applied interferential current with carbon-silicone pad electrodes (5x5 cm) and exercise therapy. Group 3 (control group): The patients in this group have performed only exercise therapy.

Blinding (investigator's opinion)

Single blinded

Blinding description

Casual randomization using sealed numbered envelopes without strata or blocks was performed by an administrative assistant. The same physician blinded to randomization evaluated all the patients before treatment, and on the first and twelfth week after the end of the treatments. Patients were not blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Turgut Özal Üniversitesi Tıp Fakültesi Etik Kurulu

Street address

Alparslan Türkeş Cad. Cad. No:57 Emek

City

Ankara

Postal code

06510

Approval date

2015-01-12, 1393/10/22

Ethics committee reference number

0000-5894-2356

Health conditions studied

1

Description of health condition studied

Low back pain (Pain between 12th rib and gluteal fold)-nonspesific origin

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

pain intensity

Timepoint

pretreatment, one week and twelve weeks after the treatment

Method of measurement

The VAS pain assessment scale was used for subjective assessment of the pain.

2

Description

Disability

Timepoint

pretreatment, one week and twelve weeks after the treatment

Method of measurement

The Oswestry questionnaire (The Oswestry Low Back Pain Disability Questionnaire, Oswestry Disability Index) was used to evaluate the functional ability of patients.

3

Description

Quality of life

Timepoint

pretreatment and twelve weeks after the treatment

Method of measurement

Short Form 36 (SF-36) was used to assess quality of life of the patients.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The patients in this group were applied interferential current with vacuum electrodes (n = 34). Four vacuum electrodes were placed so that the painful area remained in the middle. The sponges were wetted with tap water and placed in the electrode cups. To apply the electrodes to the patient, the cups were slightly squeezed, brought into contact with the skin and held there for a few minutes until suction occurred. Before application of IFT, hot pack was applied for 20 minutes to the low back. The patients in this group also received exercise therapy

Category

Treatment - Devices

2

Description

Intervention group 2: The patients in this group were applied interferential current with carbon-silicone pad electrodes (5x5 cm) (n = 34). Treatment of subjects with bilateral LBP involved paraspinal application of the cathode and anode electrodes at the lateral limits of the painful area parallel to the vertebral column. The sponges for the pad electrodes were wetted with tap water and placed them to the area to be treated using straps in the electrode cups. Before application of IFT, hot pack was applied for 20 minutes to the low back. The patients in this group also received exercise therapy.

Category

Treatment - Devices

3

Description

Control group: The patients in this group have performed only exercise therapy and hot pack was applied for 20 minutes to the low back (n = 32). Patients were requested to do core strengthening and spine stabilization exercises. The stabilization training included: activation techniques for the neutral spine position, training the activation transversus abdominis, external and internal obliques, training the activation diaphragmatic breathing, myofascial release techniques for the erector spinae muscle, exercising the coordination of superficial and deep trunk muscles, and postural and dynamic training. The exercises were performed 5 times a week. The duration of a training session was 45 min (each exercise once a day with 20 repetitions).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahi Evran University Faculty of Medicine Department of Physical Medicine and Rehabilitation

Full name of responsible person

Fatmanur Aybala Koçak

Street address

Bağbaşı Mahallesi, Şehit Sahir Kurutluoğlu Cd. No:100

City

Kırşehir

Postal code

40100

Phone

+90 386 213 45 15

Email

faybalarem@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahi Evran University Faculty of Medicine

Full name of responsible person

Fatmanur Aybala Koçak

Street address

Bağbaşı Mah. Şehir Sahir Kurutluoğlu Cad. No:100

City

Kırşehir

Postal code

40200

Phone

+90 386 213 45 15

Email

faybalarem@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Ahi Evran University Faculty of Medicine
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
Ahi Evran University Faculty of Medicine
Full name of responsible person
Fatmanur Aybala Koçak
Position
Asistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Bağbaşı Mah. Şehit Sahir Kurutluoğlu Cad. No: 100
City
Kırşehir
Province
Merkez
Postal code
40100
Phone
+90 386 213 45 15
Fax
Email
aybala.kocak@ahievran.edu.tr

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahi Evran University Faculty of Medicine
Full name of responsible person
Fatmanur Aybala Koçak
Position
Asistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Bağbaşı Mah. Şehit Sahir Kurutluoğlu Cad. No: 100
City
Kırşehir
Province
Merkez
Postal code
40100
Phone
+90 386 213 45 15
Fax
Email
aybala.kocak@ahievran.edu.tr

Person responsible for updating data

Contact
Name of organization / entity
Ahi Evran University Faculty of Medicine
Full name of responsible person
Fatmanur Aybala Koçak
Position
Asistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
physical medicine and rehabilitation
Street address
Bağbaşı Mah. Şehit Sahir Kurutluoğlu Cad. No: 100
City
Kırşehir
Province
Merkez
Postal code
40100
Phone
+90 386 213 45 15
Fax
Email
aybala.kocak@ahievran.edu.tr

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
Does The Application of Interferential Current Therapy with Vacuum Electrodes Provide Additional Effect in Patients with Nonspecific Chronic Low Back Pain? A Randomized Controlled Study This is a scientific study which was being conducted to evaluate effectiveness of interferential current therapy on pain, disability and quality of life in patients with chronic low back pain and to compare the advantages of application IFT with vacuum and carbon silicon pad electrodes to each other.
When the data will become available and for how long

The data will become available after publishing process.

To whom data/document is available

To the patints, to the PMR specialists, to the physioteharpist

Under which criteria data/document could be used

Data is available after getting permission from the authors.

From where data/document is obtainable

Via e-mail.

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

For a request, one can write an e-mail to the address : faybalarem@gmail.com

Comments