Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of Diadynamic current on prompt relief of pain in nonspecific low back pain in comparison with TENS

Protocol summary

Summary

Our aim is to investigate the effect of applying one session of Diadynamic current on prompt relief of pain in low back region of patients suffering from non specific low back pain. This is a clinical randomized double blind trial. It is double blind because patients will not be aware of the allocation as well as the therapist who take measurements. Patients are recruited from Firouzgar Hospital. Subjects with low back pain of no specific origin or history of spine fracture and not having any systemic diseases will be referred to physiotherapy clinic of the hospital and will be consecutively randomized into Diadynamic or TENS (tanscutaneous electrical nerve stimulation) groups using sealed envelopes. In this, participating therapist is given randomly generated treatment allocations within sealed opaque envelopes. Once a patient consents to enter the trial, an envelope is opened and the patient is then offered the allocated treatment regimen. Primary outcome measures (VAS and PPT (pressure pain threshold) of the main location of pain) will be measured before applying the currents, just after the current is off the patient, 20 minutes after and 48 hours later. Patients are asked not to use anti pain medicine 24 hours before treatment session and until the last measurement (48 hours later). TENS and Diadynamic currents will be applied using Multistimulator ,model 733 X, NOVIN company, Iran, using two electrodes. Diadynamic group will receive 5 minutes LP followed by 5 minutes CP and the TENS group will receive 15 minutes conventional TENS (120 Hz). Thirty patients, 15 in each group is estimated as the proper sample size.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021921139N1**
Registration date: **2015-05-25, 1394/03/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-05-25, 1394/03/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Iran University of Medical Sciences, Faculty of Medicine

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Diadynamic current on prompt relief of pain in nonspecific low back pain in comparison with TENS

Public title

The effect of Diadynamoc current on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patients having nonspecific low back pain 2. No systemic disease 3. No specific diagnosis could be made for low back pain(like tumor, osteoporosis,discopathy ,.....) 4. No history of fracture or surgery in low back 5. Not pregnant 6. Not having obvious mental and psychological problems Exclusion criteria: 1.Having used anti pain medicine during last 24 hours 2.Not coming for follow up 3.Not being able to tolerate ES for the desired amount of time

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City

Tehran

Postal code

Approval date

2015-02-24, 1393/12/05

Ethics committee reference number

93-04-30-25303-109299

Health conditions studied

1

Description of health condition studied

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back strain Lumbago NOS Excl.: lumbago: due to intervertebral disc displacement (M51.2) with sciatica (M54.4)

Primary outcomes

1

Description

pressure pain threshold

Timepoint

before -just after-after 20 mints of second measurement-after 48 hours

Method of measurement

algometer-kgf

2

Description

pain

Timepoint

before applying current-just after ES-after 20 mins-after 48 hours

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

Diadynamic current 5 mins LP 5 mins CP Diadynamic current is a monophasic alternating current with a frequency of 50 hertz. LP and CP are current modulations of Diadynamic produced by the device.

Category

Rehabilitation

2

Description

TENS 15 mins conventional TENS transcutenous electrical stimulation is a byphasic interrupted direct current with frequencies between 10 to 150 Hz.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person
Dr. Safoora Ebadi
Street address
Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr. Javad Ali Musavi
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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
Vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty