

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Safoora Ebadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 175 7107

Email address

ebadi.s@iums.ac.ir

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 transcutaneous 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 addressPhysical Medicine and Rehabilitation Department,
Firouzgar Hospital, Behafarin St., Karim khane zand
St.**City**

Tehran

St.

City

Tehran

Postal code**Phone**

+98 21 8214 1229

Fax**Email**

ebadi.s@iums.ac.ir; e_safoora@hotmail.com

Web page address**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

Street addressIran University of Medical Sciences ,Shahid Hemmat
Highway .Tehran,1449614535,IRAN**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceVice 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****Contact****Name of organization / entity**Iran University of Medical Sciences, Faculty of
Medicine**Full name of responsible person**

Dr. Safoora Ebadi

Position

Assistant Professor

Other areas of specialty/work**Street address**Physical Medicine and Rehabilitation Department,
Firouzgar Hospital, Behafarin St., Karim khane zand**Person responsible for scientific
inquiries****Contact****Name of organization / entity**Iran University of Medical sciences, Faculty of
Medicine**Full name of responsible person**

Dr. Safoora Ebadi

Position

Assistant professor, PhD Pt

Other areas of specialty/work**Street address**Physical Medicine and Rehabilitation Department,
Firouzgar Hospital, Behafarin St., Karim khane zand
St.**City**

Tehran

Postal code**Phone**

+98 21 8214 1229

Fax**Email**

ebadi.s@iums.ac.ir

Web page address**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*