Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of trigger point acupuncture and traditional acupuncture on low back pain.

Protocol summary

Study aim
Comparison of the therapeutic effect of traditional acupuncture with trigger point acupuncture in patients with low back pain

Design
Clinical trial with control group, with parallel groups will be done on 48 patients.

Settings and conduct
In this study, patients are divided into three groups: trigger point acupuncture, traditional acupuncture and control group. In each group, 16 patients with low back pain are referred to one of the medical centers of Shafaiehian or Firoozgar.

Participants/Inclusion and exclusion criteria
Inclusion criteria (patients who presented with pain in the lumbar region): Patients should be in the age range of 18 to 60 years. All patients should have at least one active trigger point. Besides, the patients' vas number should be more than 4. Exclusion criteria: Pregnancy, neuromuscular junction disorders, neurological defects found on electromyography, progressive neurological defects, urinary or fecal incontinence following pain, Progressive decrease in muscle strength, radicular pain, orthopedic disorders of the lumbar region, or history of lumbar surgery Rheumatologic disorders, a diagnosed history of hip and sacroiliac joint problems, known psychological disorders, or cancer.

Intervention groups
1st intervention group: trigger point acupuncture group, the treatment is performed in trigger points for up to 6 sessions, Once every two days, for 12 days. 2nd intervention group: traditional acupuncture group, the treatment, and points are determined based on the principles of Chinese medicine and meridian lines, which will be done for up to 6 sessions, Once every two days, for 12 days. Control group: patients will have only standard low back pain exercise and NSAID use.

Main outcome variables
Pain, disability, kinesiophobia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201207049636N1**
Registration date: **2021-04-23, 1400/02/03**
Registration timing: **prospective**

Last update: **2021-04-23, 1400/02/03**
Update count: **0**

Registration date
2021-04-23, 1400/02/03

Registrant information

Name
Fatemeh sadat Taghizadeh mayani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8848 1704

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taghizadehf892@gmail.com

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of trigger point acupuncture and traditional acupuncture on low back pain.

Public title

Comparison of the effect of trigger point acupuncture and traditional acupuncture on low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Of the patients who presented with complaints of low back pain, 48 patients were studied. Patients should be in the age range of 18 to 60 years. All patients should have at least one active trigger point. Patients must have a vas (visual analog scale) score more than 4.

Exclusion criteria:

Pregnancy Neuromuscular junction disorders Neurological defects found in electromyography Progressive neurological defects Urinary or fecal incontinence following pain Progressive decrease in muscle strength Lumbar orthopedic disorders or a history of lumbar surgery Rheumatologic disorders Diagnosed history of hip and sacroiliac joint problems Known psychological disorders Cancer

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

48 identical envelopes are prepared for randomization, The name of the intervention (types of intervention) is evenly placed in each envelope (16 envelopes per intervention). After closing the envelopes, the envelopes are shuffled so that the sequence of interventions is not clear. Each participant randomly selects one of the envelopes And after opening the envelope, the examiner will perform the type of treatment based on the treatment in the envelope.

Blinding (investigator's opinion)

Not 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, Hemmat Highway next to Milad Tower, Tehran.

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-11-04, 1399/08/14

Ethics committee reference number

IR.IUMS.FMD.REC.1399.532

Health conditions studied

1

Description of health condition studied

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain reported by the patient in the vas questionnaire

Timepoint

The beginning of the intervention, one week, one month and three months later

Method of measurement

Vas pain measurement questionnaire

Secondary outcomes

1

Description

Patient's disability based on Oswestry Disability Index (ODI) questionnaire

Timepoint

The beginning of the intervention, one week, one month and three months later

Method of measurement

ODI Disability Questionnaire

2

Description

kinesiophobia

Timepoint

The beginning of the intervention, one week, one month

and three months later

Method of measurement

kinesiophobia TSK (Tampa Scale of Kinesiophobiais) Questionnaire

Intervention groups

1

Description

1st Intervention group: In the trigger point acupuncture group, the treatment will be performed for up to 6 sessions, Once every two days, for 12 days with disposable dong-bang needles of stainless steel in the size of 0.25 × 0.4. After sterilizing with alcohol, the needle enters into the painful points, which are called trigger points. The needles are inserted by the guide tube in the marked painful points and the insertion depth of the needles is 15 to 30 mm. Which remain in place for 20 minutes per session, while at the 10th minute the needles are rotated for re-stimulation.

Category

Treatment - Other

2

Description

2nd Intervention group: In the traditional acupuncture group, treatment is done for up to 6 sessions, Once every two days, for 12 days and points have been determined based on the principles of Chinese medicine and meridian lines that these points in low back pain will include BL20-BL23-ST40-BL63-SP3-SP10-LIV6-P6-P7. In these patients, disposable Dong-Bang stainless steel needles in the size of 0.25 × 0.4 are inserted after sterilizing the points with alcohol cotton by the guide tube. The insertion depth of the needles is 15-30 mm and remains for twenty minutes. The needles in the traditional acupuncture group must be rotated and manipulated in place to achieve a feeling of numbness and heaviness or temporary burning at the site, which is called de qi sensation.

Category

Treatment - Other

3

Description

Control group: In the control group, patients will have only standard low back pain exercise and NSAID use.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Korosh Mansori

Street address

Firoozgar Hospital, Beh Afarin St., Karim Khan St., Valiasr Sq., Tehran.

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2

Recruitment center

Name of recruitment center

Shafayahiain hospital

Full name of responsible person

Korosh Mansori

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Shafayehiaian Educational and Medical Center,Mojahedin-e-Islam St., Baharestan Square,Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abbas Motavalian

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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Korosh Mansori
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Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Table of data obtained from the mentioned questionnaires
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of documents is allowed only by mentioning the source.

From where data/document is obtainable

Dr. Kourosh Mansouri, Department of Physical Medicine and Rehabilitation, Shafaiehian Hospital, Baharestan Square, Tehran, 09156538667, taghizadehf892@gmail.com.

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

The data is provided to the individual as soon as it is authenticated.

Comments