

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of lumbopelvic manipulation on the central nervous system plasticity in non-specific chronic low back pain patients with sacroiliac joint origin by magnetic resonance spectroscopy technique.

Protocol summary

Study aim

The aim of this study is to investigate the effect of lumbar spinal manipulation on the neurophysiology of the brain or neuroplasticity in neuronal surfaces in chronic non-specific low back pain patients with using a technique for measuring brain metabolites at the level of neurons by H- Check the MRS as a precise and preferred method.

Design

Sample size using Gx power software based on previous studies and the basis of Glx (Glu + Gln) metabolism and taking $d = 0.06$, $\alpha = 0.05$ and $\beta = 0.2$ in each group 8 people were appointed. Depending on the possibility of removal and removal of samples at a rate of 20% in the treatment group of 10 people and at a rate of 45% in the treatment group, 15 are studied. Samples include non-specific chronic low back pain individuals aged 20 to 50 years. Samples are divided into two treatment and Quasi-treatment groups based on random allocation method. Patients and the H-MRS imaging operator and an examiner were not aware of the groups being studied.

Settings and conduct

Patients with low back pain referred to clinics and referrals are examined by a specialist physician and, if they are eligible, will be included in the study. Patients are randomly divided into two groups: test and control. Initially, demographic information, an intensity of pain was assessed by NRS and their functional ability according to the Oswestry Disability Index questionnaire, and then information related to the metabolic map of the brain was determined using the H-MRS technique. The first group had 3 sessions of lumbopelvic manipulation treatment, and patients in the second group undergo 3 sessions of spinal alignment similar to the lumbopelvic manipulation technique. Both groups are studied at the Faculty of Rehabilitation, Shiraz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients include men and women with chronic non-specific low back pain for more than three months in the age range of 20 to 50 years, pain intensity in the waist region of at least 3, and a maximum of 7 units of the pain assessment unit by NRS (numerical rating scale), positive three Tests or more of the sacroiliac joint assessment tests (Distraction Test, Compression Test, Thigh Thrust Test, Gaenslen Test, FABER Test, and Sacral Thrust Test) have not been treated for the last three months, and will be included in the study. Exclusion criteria: Patients with chronic low back pain with specific neurologic origin and specific pathology (tumors and ...), patients with noregular and rheumatoid disorders, diabetes, patients with fractures of the ribs, vertebrae and pelvis, periosteum syndrome, abdominal aortic aneurysm, neoplasm, Neuropathy and radiculopathy, osteoporosis, fibromyalgia, pain in other areas of the body, injury and the use of ongoing drug therapy during the study, those who use antidepressants and anxiety drugs, as well as patients with non-specific chronic low back pain who underwent the last three months Treatments.

Intervention groups

The first group received 3 sessions of lumbopelvic spinal manipulation and the patients in the second group under 3 sessions of the spine position are similar to the manipulation of the lumbar and pelvis.

Main outcome variables

1. Severity of pain 2. Functional Ability 3. Metabolic map of the cortex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150923024149N15**

Registration date: **2018-01-05, 1396/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-05, 1396/10/15**
Update count: **0**

Registration date
2018-01-05, 1396/10/15

Registrant information

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-12-23, 1396/10/02

Expected recruitment end date
2019-12-23, 1398/10/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effects of lumbopelvic manipulation on the central nervous system plasticity in non-specific chronic low back pain patients with sacroiliac joint origin by magnetic resonance spectroscopy technique.

Public title

effect of lumbopelvic manipulation on neuroplasticity in non specific chronic low back pain

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

patients with chronic non specific low back pain Age between 20 and 50 years pain NRS between 3-7 3 or more positive test of SIJ test(ditraction test, compression test, thigh trust test, geanslen test,FABER test and sacral trust test) They have not been treated for the last three months

Exclusion criteria:

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly(block randomization) assigned to two groups of test and control by Random Allocation Software Software 2.0.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of the type of treatment they receive. Assessments performed before and after treatment by an evaluator who is not aware of the type of treatment. Statistical analysis is carried out by a statistician who is unaware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellery for Research Office, Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Blvd, Shiraz

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Province

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Postal code

14336 - 71348

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number

IR.SUMS.REC.1396.139

Health conditions studied

1

Description of health condition studied

non specific chronic low back pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified, Backache NOS

Primary outcomes

1

Description

brain metabolite

Timepoint

pre and 5 weeks post intervention

Method of measurement

magnetic resonance spectroscopy

Secondary outcomes

1

Description

pain

Timepoint

pre and 5 weeks post intervention

Method of measurement

numerical rating scale

Intervention groups

1

Description

Test group: They are asked to not use any medication during the course of the study. In this stage of treatment, the test group receives 3 sessions of lumbar and pelvic spinal manipulation.

Category

Treatment - Other

2

Description

Quasi-test: They are asked to not use any medication during the course of the study. At this stage, patients undergo 3 sessions of spinal alignment, similar to the lumbopelvic spinal manipulation.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

neurological, orthopedics and rehabilitation clinic

Full name of responsible person

Daryoush Didehdar

Street address

Shiraz School of Rehabilitation Sciences, Abiverdy1 street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Dr. Hashemi

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Zand street , central building of Shiraz university of medical sciences

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh Kamali

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Information on the outcome of metabolic map of the brain after the removal of the patient's profile

When the data will become available and for how long

After completing the study

To whom data/document is available

Rehabilitation and Neuroscience Researchers

Under which criteria data/document could be used

Do the same study or in line with the recent study

From where data/document is obtainable

Shiraz Rehabilitation Sciences School

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

Request from the library and the conductor of the study

Comments