Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, α = 0.05 and β = 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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Name of organization / entity
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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

City
Shiraz

Province
Fars

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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71946-33669
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daryoush1383@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz university of medical sciences
Full name of responsible person
Dr. Hashemi
Street address
Zand street , central building of Shiraz university of medical sciences
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Fax
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hashemib@sums.ac.ir
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
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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