

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of lumbar manipulation on neurometabolites of the thalamus in non-specific chronic low back pain patients

Protocol summary

Study aim

Investigating the effect of lumbar manipulation on neurometabolites of the thalamus in non-specific chronic low back pain patients

Design

In this clinical trial study, 16 patients with non-specific chronic back pain will be subjected to manipulation treatment without randomization, and will be compared with control group(16 healthy people).

Settings and conduct

Patients with back pain referred to clinics affiliated and not affiliated with Behbahan University of Medical Sciences and referred by a specialist doctor were examined and participated in the study if they were eligible. After registering the metabolic map of the thalamus, the patients enter the treatment stage. In this stage of treatment, patients receive only 3 treatment sessions of lumbar and pelvic spine manipulation in one day. 5 weeks after manipulation treatment, information related to pain , functional ability and brain metabolic map will be collected again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 16 patients with non-specific chronic back pain for more than three months in the age range of 20 to 50 years and 16 healthy people without any pain in the age range of 20 to 50 years. Exclusion criteria: patients with chronic back pain of specific origin, as well as patients with non-specific chronic back pain who were treated in the last three months.

Intervention groups

Patients were treated with lumbar and pelvic manipulation, and healthy people did not receive any intervention.

Main outcome variables

The level of neurometabolites of the thalamus, the level of pain intensity and functional disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230103057029N1**

Registration date: **2023-01-30, 1401/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-30, 1401/11/10**

Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Daryoush Didehdar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 148 7091

Email address

dary1358@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-03-18, 1401/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lumbar manipulation on neurometabolites of the thalamus in non-specific chronic low back pain patients

Public title

The effect of lumbar manipulation on neurometabolites of the thalamus in non-specific chronic low back pain patients

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

16 patients with non-specific chronic back pain for more than three months, in the age range of 20 to 50 years 16 healthy people without any pain in the age range of 20 to 50 years.

Exclusion criteria:

Patients with chronic back pain with specific neurological origin and specific pathology (tumor, etc.), patients with neurological and rheumatoid disorders, diabetes, patients with broken ribs, vertebrae, and pelvis, tailbone syndrome, abdominal aortic aneurysm, neoplasm, neuropathy and radiculopathy, osteoporosis, fibromyalgia, pain in other areas of the body, injury and use of drug during the study. People who used antidepressants and anxiety medications Patients with non-specific chronic back pain who were treated for the last three months.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Behbahan Faculty of Medical Sciences

Street address

Behbahan Faculty of Medical Sciences, Shahid Zibayenejad Ave, Behbahan.

City

Behbahan

Province

Khuzestan

Postal code

7576198664

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

IR.BHN.REC.1401.058

Health conditions studied

1

Description of health condition studied

Unspecific Chronic Low Back Pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified

Primary outcomes

1

Description

Thalamus Neurometabolites

Timepoint

Before and 5 weeks after the intervention

Method of measurement

Recording the neurometabolic map of the thalamus by magnetic resonance spectroscopy (MRS)

Secondary outcomes

1

Description

Pain Intensity

Timepoint

Before and 5 weeks after the intervention

Method of measurement

Numerical Rating Scale

Intervention groups

1

Description

Intervention group: spinal manipulation of lumbar and pelvic. Patients will receive 3 sessions of manipulation therapy (every other day) of the lumbar spine and pelvis

Category

Treatment - Other

2

Description

Control group: Healthy people Whiteout intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Behbahan Faculty of Medical Sciences

Full name of responsible person

Daryoush Didehdar

Street address

Shahidzadeh hospital, Shahid Zibayeenejad Avenue,
Behbahan Faculty of Medical Sciences

City

Behbahan

Province

Khouzestan

Postal code

6361796819

Phone

+98 61 5283 5094

Email

Dary1358@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behbahan University of Medical Sciences

Full name of responsible person

Dr Sabaghan

Street address

Shahidzadeh hospital, Shahid Zibayeenejad Avenue,
Behbahan Faculty of Medical Sciences

City

behbahan

Province

Khouzestan

Postal code

6361796819

Phone

+98 61 5283 5094

Email

Dary1358@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Behbahan 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

Behbahan University of Medical Sciences

Full name of responsible person

Daryoush Didehdar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Shahidzadeh hospital, Shahid Zibayeenejad Avenue,
Behbahan Faculty of Medical Sciences

City

Behbahan

Province

Khouzestan

Postal code

7576198664

Phone

+98 917 148 7091

Email

dary1358@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Behbahan University of Medical Sciences

Full name of responsible person

Daryoush Didehdar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Shahidzadeh hospital, Shahid Zibayeenejad Avenue,
Behbahan Faculty of Medical Sciences

City

Behbahan

Province

Khouzestan

Postal code

7576198664

Phone

+98 931 936 0791

Email

dary1358@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Behbahan University of Medical Sciences

Full name of responsible person

Daryoush Didehdar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Shahidzadeh hospital, Shahid Zibayeenejad Avenue,
Behbahan Faculty of Medical Sciences

City

Behbahan

Province

Khuzestan

Postal code

7576198664

Phone

+98 936 931 0791

Email

dary1358@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available