

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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,  
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6361796819

**Phone**

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**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,  
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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**

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**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Behbahan University of Medical Sciences

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**Position**

Assistant Professor

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## 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

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## 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