

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of two caudal-epidural methods and regional myofascial injection in patients with back pain

#### Protocol summary

##### Study aim

comparing the reduction of back pain, the level of impact on the improvement of quality of life and satisfaction in patients with myofascial pain syndrome who underwent caudal-epidural injection and those with corticosteroid injection in trigger points under ultrasound guidance.

##### Design

sample size:  $n = C \times [(P_1(1 - P_1) + P_2(1 - P_2)) / (P_2 - P_1)^2]$   $n=30$  For control group, 30 people are considered in the plan.

##### Settings and conduct

This clinical trial, after obtaining permission from the Ethics Committee of Shahid Beheshti University of Medical Sciences, is conducted on 60 patients with myofascial pain syndrome in chronic back pain between the ages of 20 and 75 in Imam Hossein and Akhtar Hospital.. After informing the patients, written informed consent will be obtained from them. The course of pain of patients in two groups is followed by caudal-epidural injection and trigger point for 6 weeks.

##### Participants/Inclusion and exclusion criteria

Participants: women and men with myofascial pain syndrome in back pain aged 20 to 75 years  
People excluded: Patients with diabetes, heart failure, hypertension, seizure history, sensitivity to local anesthesia, skin diseases, back surgery and drug addiction

##### Intervention groups

In one group, corticosteroid injection and local anesthesia (2 mg of ropivacaine) were performed under ultrasound guidance in the caudal-epidural area. In control group, with the same dose as the first group under ultrasound guidance in trigger points.

##### Main outcome variables

The main outcome variables are sleep quality, stress and anxiety, and deep muscle pain.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241017063397N1**

Registration date: **2024-12-15, 1403/09/25**

Registration timing: **prospective**

Last update: **2024-12-15, 1403/09/25**

Update count: **0**

##### Registration date

2024-12-15, 1403/09/25

##### Registrant information

##### Name

Maryam Nasoohi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2209 1492

##### Email address

nasoohi\_m@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-12-21, 1403/10/01

##### Expected recruitment end date

2025-08-23, 1404/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of two caudal-epidural methods and regional myofascial injection in patients with back pain

### Public title

Effect of caudal-epidural analgesia in back pain

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Women and men with myofascial pain syndrome in back pain aged 20 to 75 years

#### Exclusion criteria:

People with diabetes, heart failure, blood pressure, skin diseases, back surgery, seizures and drug addiction

### Age

From **20 years** old to **75 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Crossover

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of shahid beheshti University of Medical Sciences

##### Street address

saadat abad

##### City

Tehran

##### Province

Tehran

##### Postal code

1997989518

#### Approval date

2024-10-27, 1403/08/06

#### Ethics committee reference number

IR.SBMU.MSP.REC.1403.403

## Health conditions studied

### 1

#### Description of health condition studied

BACK PAIN

#### ICD-10 code

G97.1

#### ICD-10 code description

Other reaction to spinal and lumbar puncture

## Primary outcomes

### 1

#### Description

low back pain

#### Timepoint

6 WEEKS

#### Method of measurement

VAS

## Secondary outcomes

### 1

#### Description

VAS score

#### Timepoint

6 weak

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Women and men with myofascial pain syndrome in low back pain

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akhtar hospital

##### Full name of responsible person

Mahshid Ghasemi

##### Street address

Fereshteh avenue

##### City

Tehran

##### Province

Tehran

##### Postal code

0000000000

##### Phone

+98 21 2200 1072

**Email**

nasoohi\_m@yahoo.com

**2**

**Recruitment center**

**Name of recruitment center**

Emam hossein hospital

**Full name of responsible person**

Dr. Mehrdad Taheri

**Street address**

nezam abad

**City**

tehran

**Province**

Tehran

**Postal code**

0000000000

**Phone**

+98 21 7343 3000

**Email**

nasoohi\_m@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mahmoud Khodadoost

**Street address**

Velenjak- koodakyar St

**City**

Tehran

**Province**

Tehran

**Postal code**

0000000000

**Phone**

+98 21 23871

**Email**

nasoohi\_m@yahoo.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Shahid Beheshti Medical Science

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Nasoohi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**City**

Tehran

**Province**

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**Postal code**

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**Phone**

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**Email**

nasoohi\_m@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahshid Ghasemi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

pain

**Street address**

Akhtar hospital

**City**

tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 2200 1072

**Email**

nasoohi\_m@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Maryam Nasoohi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

saadat abad

**City**

Tehran

**Province**

Tehran

**Postal code**

0000000000

**Phone**

+98 21 2209 1492

**Email**

nasoohi\_m@yahoo.com

**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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Comparison of two caudal-epidural methods and regional myofascial injection in patients with back pain

**When the data will become available and for how long**

Aftar 1404-1405

**To whom data/document is available**

Anesthesiologists and pain fellowship

**Under which criteria data/document could be used**

The data can be helpful in generalizing and increasing samples and final results in similar studies.

**From where data/document is obtainable**

Scientific sites such as PubMed or email to the researcher

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

If the article cannot be accessed, email should be sent to the researcher.

**Comments**