

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

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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

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Phone

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

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Subspecialist

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pain

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

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