

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation the effects of clacitonin transforaminal epidural injection with caudal epidural injection in patients with degenerative spinal canalstenosis; a double-blinded randomized clinical trial

Protocol summary

Study aim

Evaluation the effects of clacitonin transforaminal epidural injection with caudal epidural injection in patients with degenerative spinal canalstenosis

Design

Clinical trial with control group, with parallel groups, double blinded, randomized, phase 3

Settings and conduct

This double-blinded phase 3 clinical trial will be conducted on 40 patients in two groups (20 patients in the calcitonin epidural caudal group and 20 patients in the transforaminal epidural calcitonin group) by randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic low back pain with a history of more than six months with or without dissemination to the lower extremity, Moderate to high pain (pain score over 3), Age between 40 to 70 years, Lack of proper response to drug treatments and conservative for three months, Absence of protruding disc, Severe channel tightness, Lack of reduction in vertebral height be more than 60%. Exclusion criteria: Severe spinal deformity, Spinal tumors, Spinal fracture, Local or systemic infection, Anticoagulant drug use, History of severe mental illness, Pregnancy and lactation, Patient dissatisfaction

Intervention groups

First intervention group: In the calcitonin epidural caudal group, calcitonin will be injected with a dose of 50 IU (Caspitantamin Company). Second intervention group: In the clacitonin transforaminal epidural group, calcitonin will be injected with a dose of 50 IU (Caspitantamin Company).

Main outcome variables

Pain, Inability to stand due to pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N29**

Registration date: **2021-04-21, 1400/02/01**

Registration timing: **prospective**

Last update: **2021-04-21, 1400/02/01**

Update count: **0**

Registration date

2021-04-21, 1400/02/01

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

p-rahimzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-30, 1400/02/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of clacitonin transforaminal epidural injection with caudal epidural injection in patients with degenerative spinal canalstenosis; a double-blinded randomized clinical trial

Public title

Comparing the clacitonin transforaminal epidural injection with caudal epidural injection in degenerative spinal canalstenosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic low back pain with a history of more than six months with or without dissemination to the lower extremity Moderate to high pain (pain score over 3) Age between 40 to 70 years Lack of proper response to drug treatments and conservative for three months Absence of protruding disc Severe channel tightness Lack of reduction in vertebral height be more than 60%

Exclusion criteria:

Severe spinal deformity Spinal tumors Spinal fracture Local or systemic infection Anticoagulant drug use History of severe mental illness Pregnancy and lactation Patient dissatisfaction

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients, using random allocation software, were randomly divided into clacitonin transforaminal epidural injection with caudal epidural injection. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and the statistical analyzer were unaware that the patient was exposed to the clacitonin transforaminal epidural injection with caudal epidural injection. The groups are provided to the statistical analyzer in the form of codes A and B for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences.

Street address

Vice chancellor for research, Iran University of Medical Sciences, beside Milad Tower, Hemat exp way

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2021-04-18, 1400/01/29

Ethics committee reference number

IR.IUMS.REC.1400.092

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

Four times including two weeks later, 1 month, 3 months and 6 months after surgery

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Inability to stand due to pain

Timepoint

Four times including two weeks later, 1 month, 3 months

and 6 months after surgery

Method of measurement

Oswestry Low Back Pain Disability questionnaire

Intervention groups

1

Description

Intervention group 1: In the calcitonin epidural caudal group, calcitonin will be injected with a dose of 50 IU (Caspitantamin company).

Category

Treatment - Drugs

2

Description

Intervention group 2: In the clacitonin transforaminal epidural group, calcitonin will be injected with a dose of 50 IU (Caspitantamin company).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Poupak Rahim Zadeh

Street address

Department of pain, 4th Floor, Hazrat-E-Rasool Hospital, Iran University of Medical Sciences, Niayesh "St.", Sattarkahn "Ave.", Tehran, Iran

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poupak_rah@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abas Motavalian

Street address

Iran University of Medical Sciences, Hemmat highway

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Tehran

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1433933111

Phone

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Email

poupak_rah@hotmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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