Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of Medial Branch Block with Facet Joint Injection under Ultrasonography-Guide in patient with chronic low back pain

Protocol summary

Study aim

Comparison of the Effectiveness of Medial Branch Block with Facet Joint Injection under Ultrasonography-Guide in patient with chronic low back pain

Design

Two arm parallel group clinical trial with single blinded block randomization.

Settings and conduct

This study is single blind randomized clinical trial about chronic low back pain that is done in Firuzgar hospital.

Participants/Inclusion and exclusion criteria

Patients were included if they: were more than 18 years old; had axial non radicular refractory low back pain more than 3 Month; had para spinal pain with local tenderness of Facet joint is exacerbated by extension and lateral rotation; had normal MRI. Patients were excluded if they: had neurological disorder; had tumor; had general infection or skin infection of injection Site; had coagulopathy; had sensitivity to lidocaine and steroid; had history of back surgery; had Pregnancy;' were non-cooperative patient; had more than tow level or bilateral involvement of Facet joints

Intervention groups

First randomized group goes under Medial Branch Block in 2 Levels (same and above level) under Ultra sound-Guided with 2miligram(mg) Lidocaine and 1mg Triamcinolone and second randomized group goes under Facet joint injection in 2 Levels (same and above level) under Ultra sound-Guided with 2miligram(mg) Lidocaine and 1mg Triamcinolone.

Main outcome variables

The effect of low back pain in ability of daily living, severity of sign

General information

Reason for update

Actual recruitment dates were added to complete the trial record. Recruitment began later than originally anticipated due to delays in study initiation, interruptions during the COVID-19 pandemic, and institutional circumstances. No participant was enrolled before the actual recruitment start date reported here.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038889N1**
Registration date: **2018-07-31, 1397/05/09**
Registration timing: **prospective**

Last update: **2026-09-12, 1405/06/21**
Update count: **2**

Registration date

2018-07-31, 1397/05/09

Registrant information

Name

Amirhossein Sadeghian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8846 8248

Email address

sa.amirhossein@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

2018-08-01, 1397/05/10

Actual recruitment end date

2023-08-01, 1402/05/10

Trial completion date

2023-08-22, 1402/05/31

Scientific title

Comparison of the Effectiveness of Medial Branch Block with Facet Joint Injection under Ultrasonography-Guide in patient with chronic low back pain

Public title

Effect of Medial Branch Block and Facet Joint Injection in treatment of chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above the 18 years old. Axial Non Radicular Low Back Pain that Conservative Treatment more than 3 Month is failed . Para Spinal Pain with Local Tenderness of Facet Joint that exacerbated with Extension and Lateral Rotation. MRI is Normal.

Exclusion criteria:

Neurological Disorder Tumor General Infection or Skin Infection of Injection Site Coagulopathy Sensitivity to Lidocaine and Steroid Previous Surgery of Back Pregnancy Non-Cooperative Patient More than two level or bilateral involvement of Facet joints

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization in which each member of the community has equal and independent chance to be selected. For randomization, the random block method with quad and dual blocks will be used. According to the sample size of 30 peoples, six blocks of quad and four blocks of dual will be generated and numbered using the tracks method. Using blocks of random numbers, the blocks are located at the other end of the screen and will form the sequence of allocation of patients to the treatment groups. Therefore, before choosing participants, the type of treatment that will be received will be unaware and the random sequence produced during the study will be immune from prediction.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patient do not know in witch Randomized Group(Facet Joint Group or Medial Branch Block) are entered.

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 Science

Street address

Shahid Hemat Highway,Ethics committee of Iran University of Medical Science,Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.IUMS.FMD.REC

Health conditions studied

1

Description of health condition studied

Lumbar facetogenic pain syndrome

ICD-10 code

M54.8

ICD-10 code description

Other dorsalgia

Primary outcomes

1

Description

The effect of low back pain on Ability of Daily Living

Timepoint

Zero, Four weeks

Method of measurement

Oswestry Disability Index questioner

2

Description

Severity of sign

Timepoint

Zero, One week , Four weeks ,Twelve weeks

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Lumbar facet joint injection with mixture of Lidocaine and Corticosteroid under Ultra sound Guide by Physical Medicine and Rehabilitation Expert
Category
Treatment - Other

2

Description
Intervention group 2: Lumbar Medial branch block with mixture of Lidocaine and Corticosteroid under Ultra sound Guide by Physical Medicine and Rehabilitation Expert
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firuzgar hospital
Full name of responsible person
Amirhossein Sadeghian
Street address
Firuzgar hospital,Behafarin st, Karimkhan st, Valiasr sq,Tehran
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Sponsors / Funding sources

1

Sponsor
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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
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
Dr Arash Babaei
Position
Associate Professor of Physical Medicine and Rehabilitation
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Specialist
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Person responsible for updating data

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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
All of patients data after non-identification have possibility of sharing
When the data will become available and for how long
After six months of results print
To whom data/document is available
For researchers work in University and Academic institutes are available
Under which criteria data/document could be used
with mention of source can be printed by other researchers
From where data/document is obtainable
Dr Amirhossein Sadeghian-sa.amirhossein@yahoo.com
What processes are involved for a request to access data/document
After authentication,data will be available
Comments