

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180227038889N1**  
Registration date: **2018-07-31, 1397/05/09**  
Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-28, 1397/12/09**

Update count: **1**

##### 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

2018-09-23, 1397/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### 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**

#### 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1600

**Email**

h\_firoozgar@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr, Seyed Ali Javad Musavi

**Street address**

5Floor, Shahid Hemat High Way, Iran university of medical science, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8214 1201

**Email**

admins@iums.ac.ir

**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

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Firuzgar hospital, Behafarin st, Karimkhan st, Valiasr sq, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1229

**Email**

babaei-ghazani.a@iums.ac.ir

**Person responsible for scientific 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

**Latest degree**

Specialist

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**Phone**

+98 21 8214 1229

**Email**

babaei-ghazani.a@iums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Amirhossein Sadeghian

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Department of Physical Medicine and Rehabilitation,  
Firuzgar Hospital, Valiasr Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1229

**Email**

sa.amirhossein@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**

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**