

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Ultrasound-Guided Medial-Branch Block for pain management of Lumbar facet joints pain in patients referral to Akhtar hospital between 2012-2013 years.

#### Protocol summary

##### Summary

**Objectives:** This study is aimed to evaluate ultrasound-Guided Medial-Branch Block for Lumbar facet joints in patients with chronic low back pain in the facet joint region who were referred to pain clinics of Akhtar Hospitals between 2012-2013 years. **Design:** Prospective clinical trial. **Setting and conduct :** Tertiary regional and teaching hospital. **Participants including major eligibility criteria:** patients with chronic low back pain in the facet joint region who were referred to pain clinics of Akhtar Hospitals between 2012-2013 years, were included. **Intervention:** Local anesthesia was provided by injection of 1% lidocaine 1 mL. A 21-gauge, 9-cm spinal needle was directed in the ultrasound plane at an angle of approximately 45 to 60 degrees to the skin and was advanced laterally and medially until the needle tip reached the target and bony contact was felt. A longitudinal paravertebral ultrasound view was then obtained to verify the position of the needle at the cephalad margin of the transverse process. C-arm fluoroscopy was performed to assess the precision of the needle location. Needle position was evaluated according to the International Spinal Society guidelines and considered to be in target, if it was slightly medial to the lateral margin of silhouette of the superior articular process (SAP) in the posteroanterior view and high on the eye of the Scotty dog in the oblique view. If the needle was out of the radiologic target or invisible in the sonography, it was repositioned under fluoroscopy guidance before the drug was injected. Then, For all patients were injected mix of triamcinolone acetone 40 mg and 1% lidocaine 1 mL at L1-L2, L2-L3, L3-L4, L4-L5, L5-S1 levels on the right/left side for treatment of lumbar facet joint pain. **Main outcome measures (variables):** Visual analog scale; Oswestry disability index score; Success rate; Time of needle placement; Patient request for analgesia.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201306168435N6**

Registration date: **2013-07-09, 1392/04/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-09, 1392/04/18

##### Registrant information

##### Name

Seyed Masoud Hashemi

##### Name of organization / entity

Department of Anesthesiology and Pain

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2261 2252

##### Email address

mohammadinasab@alumnus.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences and Health Services

##### Expected recruitment start date

2012-04-03, 1391/01/15

##### Expected recruitment end date

2013-03-15, 1391/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Ultrasound-Guided Medial-Branch Block for pain management of Lumbar facet joints pain in patients referral to Akhtar hospital between 2012-2013 years.

**Public title**

Management of chronic lumbar pain with ultrasound-guided for block of lumbar facet joints

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Main inclusion criteria: Age > 18 years old; Symptoms of chronic low back pain for more than three months; Persistent low back pain with or without pain radiating to the upper leg; Focal tenderness over the lumbar spine joint; Hyperextension pain; Absence of neurological defects; Contraindication of lumbar surgery; Absence of radicular syndrome; No respond to traditional treatments; Signing consent to participate in the study. Main exclusion criteria: Lumbar radicular pain; Disc with radicular symptoms of pain associated with radiological or neurological tests; Coagulation disorders; Allergy to local anesthetic solution; Malignancy; Psychiatric problems and poor patient cooperation; Speech problems; Pregnancy; Surgery indication; Local skin infection at the operative site; Spinal deformities; Body mass index > 29 kg/m<sup>2</sup>

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

**Street address**

Tabnak S.

**City**

Tehran

**Postal code****Approval date**

2012-01-13, 1390/10/23

**Ethics committee reference number**

P/1390-10-23

**Health conditions studied****1****Description of health condition studied**

Chronic low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Diagnosis Low back pain

**Primary outcomes****1****Description**

Time of needle placement

**Timepoint**

During procedure

**Method of measurement**

The time from insertion into skin until fluoroscopic confirmation

**2****Description**

Patient request for analgesia

**Timepoint**

Before, immediately after, and one week, 4 and 6 weeks after the procedure

**Method of measurement**

Based on the patient's request

**3****Description**

Disability measurement

**Timepoint**

Before, immediately after, and one week, 4 and 6 weeks after the procedure

**Method of measurement**

Oswestry disability index score

**4****Description**

Success rate

**Timepoint**

Immediately after the procedure

**Method of measurement**

Pain relief more than 50%

## 5

### Description

Pain score

### Timepoint

Before, immediately after, and one week, 4 and 6 weeks after the procedure

### Method of measurement

Visual analog scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Ultrasound guided nerve block

#### Category

Treatment - Other

### 2

#### Description

Control group: Conventional fluoroscopy guided nerve block

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akhtar Hospital

##### Full name of responsible person

Seyed Masoud Hashemi MD

##### Street address

Elahiye St.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences and Health Services

##### Full name of responsible person

Mohammad Rahmati Roodsari MD

##### Street address

Parvaneh St., Yaman St., Shahid Chamran Expressway

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences and Health Services

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Akhtar Hospital

#### Full name of responsible person

Seyed Masoud Hashemi

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

Elahiyeh St.

#### City

Tehran

#### Postal code

#### Phone

+98 21 2261 2252

#### Fax

#### Email

Dr.hashemi@sbm.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Akhtar Hospital

#### Full name of responsible person

Seyed Masoud Hashemi

#### Position

Anesthesiologist & Pain fellowship

#### Other areas of specialty/work

#### Street address

Elahiyeh St.

#### City

Tehran

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#### Fax

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Dr.hashemi@sbmu.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Akhtar Hospital

**Full name of responsible person**

Seyed Masoud Hashemi

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*