

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of transforaminal ozone injection Vs triamcinolon infiltration on chronic radicular low back pain.

Protocol summary

Summary

Objectives: The aim of this study is evaluation of effect, safety and side effect of ozone as a new modality in treatment of radicular LBP. Design and participant including major eligibility criteria and setting and conduct: The sample size is 64 patients. the including radicular low back pain patients are randomly ordered by block randomization in two group and the study is double blinded which means that patients, research evaluators and study analyzer are not aware of treatment. intervention: While performing the steroid method 20mg triamcinolone plus 5ml bupivacaine 0.2% and in the second group 10ml ozone 30mic/ml plus 5ml bupivacaine 0.2% per foramen are injecting. Main outcomes: pain score, disability index, Serum level of TNF α , physical examination and lab test (BUN, Cr , BS). in two group at end of week two and fourth intervention is repeating. at the start of study, end of week two, week fourth month three and six since start of study, pain questionnaire, owestry disability questionnaire, pain score (numerical rating scale) are accomplish and document recording. so at the start of treatment and the end of month two chronic pain biomarker TNF α and MRI are measure and results recording for analysis and comparing.

General information

Acronym

none

IRCT registration information

IRCT registration number: **IRCT201610177984N26**

Registration date: **2017-02-12, 1395/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of transforaminal ozone injection Vs triamcinolon infiltration on chronic radicular low back pain.

Public title

effect of ozone on low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria including: Radicular LBP that persistent more than 6 weeks; Root impression due to disc bulging or foraminal narrowing that confirmable in MRI; The patient age must be between 18 -70 yr old; Physical

status level I to II according to ASA physical status classification system. Valid, written consent to participate in study must be obtained; Pain score must be more than 4 according to numerical rating scale(NRS)tool; Lack of pain relieve to medication and physical therapy; Three or less nerve root must be involved. Exclusion criteria including: If coagulopathy to exist; presence of systemic or zone of needle entry point infection; Severe anatomical distortion(for example scoliosis); presence history of back surgery or device implantation; Severe psychotic disorder is co-exist; history of allergy to local anesthetics is positive; if progressive deficiency or motor deficit to exist; If malignancy, pregnancy, or history of substance abuse, HIV and /or chronic hepatitis marker positive to exist; If acute trauma; or cauda equina syndrome to exist.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Expressway corner

City

Tehran

Postal code**Approval date**

2016-09-18, 1395/06/28

Ethics committee reference number

IR.IUMS.REC.1395.28857

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

low Back Pain

ICD-10 code

M54.4

ICD-10 code description

low Back Pain with Sciatica

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

Pain

Timepoint

befor itervention will started,and the end of weeks two and four months three and six

Method of measurement

Nnmrical Rating Scale tool of pain

2**Description**

chronic pain biomarker, TNFalpha in serum.

Timepoint

befor itervention will started,and the end of month two.

Method of measurement

Venous Blood sample

3**Description**

Root Impression in MRI

Timepoint

Before intervention and the end of second month

Method of measurement

MRI imagine

Secondary outcomes**1****Description**

disability

Timepoint

befor intervention will start,the end of weeks two and four,months three and six

Method of measurement

Oswestry Disability Questionnaire

2**Description**

labratory data, BUN, Cr, Bs

Timepoint

befor intervention will start,the end of weeks two and four,months three and six

Method of measurement

Venous blood sample

3

Description

Dermatomal pain distribution, positive SLR (and degree of), reverse SLR

Timepoint

Before intervention will start, the end of weeks two and four, month three and six

Method of measurement

Pain that induced with physical examination and its distribution, degree of range of motion that induced pain,...

Intervention groups

1

Description

(10ml of 30micro/ml ozone +5ml bupivacaine 0.2%) per root.

Category

Treatment - Surgery

2

Description

20mg triamcinolone +5ml bupivacaine 0.2% per root will inject

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat- Rasul Akram Medical Complex

Full name of responsible person

Farnad Imani

Street address

Anesthesiology and pain department of Hazrat-Rasoul Medical Complex Niayesh street, Sattar-Khan Avenue.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr Mohammad Musavi.

Street address

Iran University of Medical Sciences, Hemmat highway

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, Iran University of Medical Sciences

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

Hemmat Highway Iran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position

Anesthesiology Professor, Interventional Pain fellowship

Other areas of specialty/work

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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