# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jun 2026

## Clinical trial to evaluate the effect of vitamin D supplementation on discogenic pain and sensory deficits associated with cases afflicted with lumbar disc herniation

## Protocol summary


**Summary**

Objectives: 1) Effect of vitamin D on decreasing discogenic pain. 2) Effect of vitamin D on discogenic-associated sensory deficits Design: Randomized placebo-controlled double blind clinical trial. Setting and conduct: Out-patient neurosurgery department Criteria-met patients will be informed about the nature of this study. Written informed consent will be obtained. Pre-intervention studies that will be done at clinic are as follows: 1) McGill questionnaire for sensory deficits. 2) Visual analogue score for low back pain and radicular pain severity. 3) Physical examination for detecting sensory deficits. Patients will be categorized based on their vitamin D level into three groups: Group 1) Optimum vitamin D level (32-50ng/ml) cases. Group 2) Deficient (less than 10ng/ml) and Group 3) Insufficient (less than 32ng/ml) vitamin D level cases. Each of the above-mentioned groups will be randomized based on random computer-generated numbers into 2 groups to receive either 300 000 IU vitamin D (1 ml) or distilled water (1 ml) intramuscularly. All patients will be under conservative treatment and will be prescribed 15 mg Meloxicam capsules (daily). Our study population will be warned of severe adverse side effects of vitamin D verbally and in written forms ( nausea, vomiting, abdominal pain, metallic taste, breathing difficulties.....). They will have access to emergency department in case of of side effects occurence. The conduction duration of this study will 15 days. After injection, patients will be contacted by phone every three day to assess their pain and sensory deficits by McGill questionnaire and Visual analogue score ( 5 times). Final post-treatment studies that will be carried out at clinic, will be: 1) McGill questionnaire for sensory deficits. 2) Visual analogue score for low back pain and radicular pain severity. 3) Physical examination for detecting sensory deficits. Participants eligibility criteria: Inclusion Criteria: 1) No coexistent or preexisting spine pathology (e.g. Spondylolisis, Spondylolisthesis, Infection, Tumors, Fracture) 2) Single level lumbar disc herniation. 3) Discogenic pain duration from onset up physician evaluation: less than 8 weeks. 4) Compliance with study protocol. 5) Normal Lab studies. Exclusion Criteria: 1) Daily supplementation intake of more than 800 IU of vitamin D. 2) Serum calcium level more than 10.5 md/dl. 3) Hypercalciuria ( spot urine calcium creatinin ratio more than 0.4) 4) Lymphoma, Sarcoidosis, TB, Hyperparathyroidism, Celiac disease, malabsorption syndromes, 5) Hx of renal stone. 6) Hx of inflammatory back pain. 7) Impaired renal function tests (GFR less than 30) 8) Impaired hepatic function tests. 9) Abnormal Serum Phosphorus, Alkaline phosphatase and Parathroid hormone values. 10) FBS more than 126. Intervention: Patients will receive either single-dose 300000 IU vitamin D3 (1ml) or 1 ml of distilled water intramuscularly. Outcome measures: 1) McGill questionnaire for sensory deficits. 2) Visual anlogue score for low back pain and radicular pain severity.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014050317534N1**
Registration date: **2014-06-05, 1393/03/15**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2014-06-05, 1393/03/15

**Registrant information**

**Name**

Mahsa Sedighi

**Name of organization / entity**

Shiraz University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 71 1233 0161

**Email address**
sedighi.mahsan@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**
Shiraz University of Medical Sciences

**Expected recruitment start date**
2015-01-01, 1393/10/11

**Expected recruitment end date**
2016-01-31, 1394/11/11

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Clinical trial to evaluate the effect of vitamin D supplementation on discogenic pain and sensory deficits associated with cases afflicted with lumbar disc herniation

**Public title**
Role of Vitamin D in Treatment of Lumbar Disc Herniation: Pain and Sensory Aspects

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion Criteria: 1) No coexistent or preexisting spine pathology (e.g. Spondylolisis, Spondylolisthesis, Infection, Tumors, Fracture); 2) Single level lumbar disc herniation; 3) Discogenic pain duration from onset up physician evaluation: less than 8 weeks; 4) Compliance with study protocol; 5) Normal Lab studies; Exclusion Criteria: 1) Daily supplementation intake of more than 800 IU of vitamin D; 2) Serum calcium level more than 10.5 md/dl; 3) Hypercalciuria ( spot urine calcium creatinin ratio more than 0.4); 4) Lymphoma, Sarcoidosis, TB, Hyperparathyroidism, Celiac disease, malabsorption syndromes; 5) Hx of renal stone; 6) Hx of inflammatory back pain; 7) Impaired renal function tests (GFR less than 30); 8) Impaired hepatic function tests; 9) Abnormal Serum Phosphorus, Alkaline phosphatase and Parathyroid hormone values; 10) FBS more than 126; 11) Previous spine surgery; 12) Hx of trauma; 13) Taking Anticonvulsant, Anti-TB medications or vitamin D analogs; 14) Cauda Equina syndrome that requires emergency surgical decompression.

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **380**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

### 1

**Registry name**
ثبت نشده است

**Secondary trial Id**
ثبت نشده است

**Registration date**
empty

### 2

**Registry name**
ثبت نشده است

**Secondary trial Id**
ثبت نشده است

**Registration date**
empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Shiraz University of Medical Sciences Reasearch Ethics Committee

**Street address**
Shiraz University of Medical Sciences, Zand Blvd, post code:71345-1978

**City**
Shiraz

**Postal code**
71345-1978

**Approval date**
2014-02-02, 1392/11/13

**Ethics committee reference number**
CT-P-92-6632

## Health conditions studied

### 1

**Description of health condition studied**
Lumbar Disc Herniation

**ICD-10 code**
M51.2
**ICD-10 code description**
Other specified intervertebral disc displacement

**2**

**Description of health condition studied**
Lumbar Disc Herniation
**ICD-10 code**
M51.1
**ICD-10 code description**
Lumbar and other intervertebral disc disorders with radiculopathy

## Primary outcomes

**1**

**Description**
Pain
**Timepoint**
One initial and one final assessment will be performed at clinic.during 15-day conduction period, individuals will be contacted by phone every 3 days to comlete the questionnaires.
**Method of measurement**
Visual analoque score for low back pain and radicular pain severity

## Secondary outcomes

**1**

**Description**
Sensory deficits
**Timepoint**
One initial and one final assessment will be carried out at clinic.During 15-day conduction period, individuals will be contacted by phone every 3 days to comlete the questionnaires.
**Method of measurement**
Mc-Gill questionnaire

## Intervention groups

**1**

**Description**
Name of the drug: Ampoule 25 Hydroxy Vitamin D3 Chemical composition: 25 Hydroxy Vitamin D3 Concentration: 300000 International Unit in 0ne ml. Dosage: One Ampoule Intramuscular injection Number of usage: Single-dose Duration of usage: Single
**Category**
Treatment - Other

**2**

**Description**
Deficient Vitamin D level (less than 10ng/ml)
**Category**
Treatment - Drugs

**3**

**Description**
Insufficient vitamin D level (less than 32ng/ml)
**Category**
Treatment - Drugs

**4**

**Description**
A single-dose of 300 000 IU of 25 Hydroxy vitamin D3 (1 ml) will be injected intramuscularly.
**Category**
Treatment - Drugs

**5**

**Description**
A single-dose of distilled water (1 ml) will be injected intramuscularly.
**Category**
Placebo

**6**

**Description**
Optimum vitamin D level group (32-50ng/ml)
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Chamran neurosurgery OPD clinic
**Full name of responsible person**
Mahsa Sedighi
**Street address**
Chamran Blvd
**City**
Shiraz

**2**

**Recruitment center**
**Name of recruitment center**
Dr. Ali Haghnegahdar Clinic
**Full name of responsible person**
Ali Haghnegahdar
**Street address**
3rd floor, Building number 112, Palestine Street.
**City**
Shiraz

**3**

**Recruitment center**
**Name of recruitment center**
Dena Hospital OPD clinic

**Full name of responsible person**
Mahsa Sedighi
**Street address**
Dena Hospital, Dena Ave, Satarkhan Blvd.
**City**
Shiraz

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice Chancellor for Research Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Basir Hashemi
**Street address**
Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
**City**
Shiraz
**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 Shiraz 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**
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**Fax**
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**Email**
N/A
**Web page address**
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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*