

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparing the effect of injection compared to no injection of local methylprednisolone on prevertebral soft tissue swelling during operation in patients with cervical discopathy

#### Protocol summary

##### Summary

Goal of study: The goal of this study is evaluation the effect of local methylprednisolone injection during cervical disc surgery on the prevertebral soft tissue swelling from third to seventh vertebrae. Design: This study is a randomized, single blind, clinical trial. Inclusion criteria: Myelopathy or radicular pain due to cervical disc herniation in one or two segments. Exclusion criteria: Cervical disc herniation more than two segments; history of previous surgery in same area; need to corpectomy. Sample size: Forty patients with myelopathy or radicular pain due to cervical disc herniation undergoing operation in two centers Qazvin Shahid Rajaee and Pasteur hospital. Patients by selection colored cards are divided into two equal groups. In interventional group (20 patients), at the end of operation 80 milligrams methylprednisolone is injected into the retropharyngeal and paravertebral muscles. In control group (20 patients) no injection is used. Patients are unaware of the injection or no injection of drug. In all patients, lateral neck radiography is performed one day before surgery, two days and ten days after operation later. All radiographs are evaluated by one radiologist. Primary outcome: Prevertebral soft tissue swelling based on the ratio of prevertebral soft tissue thickness to the anteroposterior diameter of vertebral body is calculated on third to seventh cervical vertebrae. Secondary outcome: Postoperative local pain and dysphagia are compared in the second and tenth day after operation in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015072123270N1**

Registration date: **2015-10-08, 1394/07/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-10-08, 1394/07/16

##### Registrant information

###### Name

Mohsen Hasani barzi

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3333 6005

###### Email address

smbarzi@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2015-08-17, 1394/05/26

##### Expected recruitment end date

2015-12-22, 1394/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of injection compared to no injection of local methylprednisolone on prevertebral soft tissue swelling during operation in patients with cervical discopathy

##### Public title

Effect of local corticosteroid injection on prevertebral soft tissue swelling in cervical disc surgery

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Patients with radiculopathy or myelopathy due to cervical disc involving one or two segments. Exclusion criteria: Cervical disc herniation more than two segments; history of previous surgery in same area; need to corpectomy; Herniated disc due to cervical trauma or infection or tumor; underlying diseases such as rheumatoid arthritis; diabetes and chronic heart or renal diseases.

### **Age**

From **20 years** old to **80 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

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

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single 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 Qazvin University of Medical Sciences

##### **Street address**

Bahonar Blvd, Qazvin, Iran

##### **City**

Qazvin

##### **Postal code**

#### **Approval date**

2014-06-02, 1393/03/12

#### **Ethics committee reference number**

20/11138/5

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Cervical disc

#### **ICD-10 code**

M50

#### **ICD-10 code description**

Cervical disc disorders

## **Primary outcomes**

### 1

#### **Description**

Prevertebral soft tissue swelling in third to seventh cervical vertebrae

#### **Timepoint**

One day before, two days after and ten days after operation

#### **Method of measurement**

Measurement by lateral cervical radiography

## **Secondary outcomes**

### 1

#### **Description**

Local pain in operation site

#### **Timepoint**

Two days and ten days after operation

#### **Method of measurement**

Visual analogue scale

### 2

#### **Description**

Dysphagia

#### **Timepoint**

Two days and ten days after operation

#### **Method of measurement**

Dysphagia scaling table

## **Intervention groups**

### 1

#### **Description**

Intervention 1: Local injection of 80 milligram methylprednisolone acetate (injectable suspension) produced by caspianamin factory into the retropharyngeal and prevertebral neck muscles by 5 milliliter syringe with insulin needle following cervical disc surgery

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention 2: In this group at the end of operation no injection into the prevertebral and retropharyngeal muscles is used.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rajae hospital

**Full name of responsible person**

Mohsen hasani barzi

**Street address**

Padegan St, Qazvin, Iran

**City**

Qazvin

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research of Qazvin University of Medical Sciences

**Full name of responsible person**

Mohsen hasani barzi

**Street address**

Bahonar Blvd, Qazvin, Iran

**City**

Qazvin

**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 of Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Mohsen hasani barzi

**Position**

Neurosurgeon

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****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*