Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 ninjection 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/د

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 caspiantamin 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
Rajaee 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
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Postal code
4321102589
Phone
+98 28 3333 6001
Fax
Email
drbarzi2002@yahoo.com
Web page address

Person responsible for scientific 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
Bahonar Blvd, Qazvin, Iran
City
Qazvin
Postal code
4321102589
Phone
+98 28 3333 6001
Fax
Email
drbarzi2002@yahoo.com
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