

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Determining the effect of methylene blue on postoperative pain and quality of life after lumbar laminectomy and discectomy

Protocol summary

Summary

This study which was performed as a triple blind clinical trial, aimed to evaluate the effect of Methylene blue on the improvement of postoperative pain and quality of life (QOL) after lumbar laminectomy and discectomy. A total of 115 patients who should be operated for lumbar spinal canal stenosis or the herniation of degenerative disc in one level or multiple levels were selected, alternatively. Methylene blue 0.5% with a dose of 1cc was injected to 56 patients (study group) and 59 other patients received normal saline for covering dura hemostasis (control group). The patients with a history of laminectomy or discectomy surgical operation who are now under a repeated surgery and also those with infection were excluded. In both groups, pain and functional QOL were evaluated before and 3 months after the surgical operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807142193N4**

Registration date: **2011-06-24, 1390/04/03**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-06-24, 1390/04/03

Registrant information

Name

Majid Reza Farrokhi

Name of organization / entity

Shiraz Neurosciences Research Center, Shiraz

University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research affairs of Shiraz University of Medical Sciences and Health Services-Shiraz University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of methylene blue on postoperative pain and quality of life after lumbar laminectomy and discectomy

Public title

Determining the effect of methylene blue on postoperative pain and quality of life after lumbar laminectomy and discectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who should be operated for lumbar spinal canal stenosis or the herniation of degenerative disc in one level or multiple levels.

Exclusion criteria: Patients with a history of laminectomy or discectomy who underwent a repeated surgery and also those with infection

Age

To 80 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 130

Randomization (investigator's opinion)

Randomized

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

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences-Zand boulevard-Shiraz

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Shiraz

Postal code

7194815644

Approval date

2011-05-28, 1390/03/07

Ethics committee reference number

CT- 90-5571

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

Postoperative pain improvement.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Severity of postoperative low back pain and radicular pain

Timepoint

Before the surgical operation and 3 months after that

Method of measurement

It was measured using visual analogue scale (VAS)

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

quality of life (QoL)

Timepoint

Before the surgical operation and 3 months after that.

Method of measurement

Oswestry low back pain (OLBP) scale

Intervention groups**1****Description**

Intervention group: Using methylene blue, 1cc, with 0.5% concentration after laminectomy or discectomy surgical operation for covering dura hemostasis

Category

Treatment - Drugs

2**Description**

Control group: Using normal saline, 1cc after laminectomy or discectomy surgical operation for covering dura hemostasis

Category

Treatment - Drugs

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

Faghihi Hospital

Full name of responsible person

Dr. Majid Reza Farrokhi

Street address

Shiraz Neurosciences Research Center-Chamran Hospital-Shiraz

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

Shiraz University of Medical Sciences

Full name of responsible person

Vice-chancellor for Research Affairs of Shiraz University of Medical Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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****Name of organization / entity**

Shiraz Neurosciences Research Center-Shiraz
University of Medical Sciences

Full name of responsible person

Dr. Majid Reza Farrokhi

Position

Neurosurgeon-Fellowship of spinal surgery-director of
Shiraz Neurosciences Research Center

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Radiologist-MRI fellowship

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mahshid Hosseini

Position

The expert of research affairs of the center

Other areas of specialty/work**Street 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