

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison effect of Dexamethasone and Morphine administration (intravenous, intrathecal and local) in pain control following lumbar spinal surgery

Protocol summary

Study aim

The comparison effect of Dexamethasone and Morphine administration (intravenous, intrathecal and local) in pain control following lumbar spinal surgery

Design

Single blinded clinical trial on 75 patients in three parallel groups

Settings and conduct

Sampling is done in Shahid Rajaei hospital to evaluate the severity of pain after lumbar spine surgery. Patients are divided in three groups of 25 cases by using colored cards.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients candidates for Discectomy, Laminectomy and fusion in more than one segment. Exclusion criteria: Trauma patients, tumor of the lumbar region, rheumatologic and metabolic diseases, cardiovascular disease, drug allergy to Morphine addiction history, non-completion of conservative treatment, previous lumbar spine surgery, BMI index at least 35, surgical complications such as surgical site infection, hematoma, and drug side effects such as apnea

Intervention groups

Group A: Put a surgery cell on dura site which impregnated with 2 mg of Morphine and 0.1 mg/kg of Dexamethasone Group B: Injection of 0.02 mg/kg Morphine and 0.1 mg/kg Dexamethasone using the interatecal method Group C: Injection of 0.1 to 0.2 mg/kg Morphine and 0.1 mg/kg Dexamethasone intravenously before closure of the surgical site

Main outcome variables

Pain after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023270N2**
Registration date: **2018-07-12, 1397/04/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-12, 1397/04/21**

Update count: **0**

Registration date

2018-07-12, 1397/04/21

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

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of Dexamethasone and Morphine administration (intravenous, intrathecal and local) in pain control following lumbar spinal surgery

Public title

The effect of Dexamethasone and Morphine administration by three methods on pain control after lumbar spinal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidates for discectomy, laminectomy and fusion in more than one segment.

Exclusion criteria:

Trauma patients, tumor of the lumbar region, rheumatologic and metabolic diseases, cardiovascular disease Drug sensitivity to Morphine Addiction history Non-completion of conservative treatment Previous lumbar spine surgery BMI index at least 35 Surgical complications such as surgical site infection Hematoma, and drug side effects such as apnea

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are divided in three groups (25 cases) by using colorful cards.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd., Qazvin

City

Qazvin

Province

Qazvin

Postal code

3413996134

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.QUMS.REC.1395.213

Health conditions studied

1

Description of health condition studied

Lumbar spinal disease

ICD-10 code

S34.10

ICD-10 code description

Unspecified injury to lumbar spinal cord

Primary outcomes

1

Description

Pain

Timepoint

At 6, 12, 24, and 48 hours after surgery

Method of measurement

Visual analogues scale

Secondary outcomes

1

Description

Vomiting and nausea

Timepoint

At 6, 12, 24 and 48 hours after surgery

Method of measurement

Observation

2

Description

Total amount of Morphine requirement

Timepoint

At 6, 12, 24 and 48 hours after surgery

Method of measurement

Interview with patient

Intervention groups

1

Description

Intervention group: Group A: Putting a surgi-cell in dura

site which impregnated with 2 mg of Morphine and 0.1 mg/kg of Dexamethasone

Category

Treatment - Drugs

2

Description

Intervention group: Group B: Injection of 0.02 mg/kg Morphine and 0.1 mg/kg Dexamethasone using the interatecal method

Category

Treatment - Other

3

Description

Intervention group: Group C: Injection of 0.1 to 0.2 mg/kg Morphine and 0.1 mg/kg Dexamethasone intravenously before closure of the surgical site

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei hospital

Full name of responsible person

Bahareh Behnam Ghader

Street address

Padegan street, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34139-96134

Phone

+98 28 3333 5800

Email

b.behnamghader6@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Bahareh Behnam Ghader

Street address

Shahid Bahonar Blvd., Qazvin

City

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Phone

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Email

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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

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Bahareh Behnam Ghader

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Padegan street, Qazvin

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr.Seyed Mohsen Hasani Barzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery
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Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Bahareh Behnam Ghader
Position
Intern
Latest degree
Medical doctor
Other areas of specialty/work
Medical Education
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments