

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the effect of administration of intrathecal Dexmedetomidine on the Spinal Cord Mori levels of apoptotic factors in patients scheduled for lumbar disc surgery

Protocol summary

Study aim

Evaluating the effect of administration of intrathecal Dexmedetomidine on the Spinal Cord Mori levels of apoptotic factors in patients scheduled for lumbar disc surgery

Design

Randomized, Not blinded, controlled, parallel group phase III clinical trial in 40 patients

Settings and conduct

This study was performed on patients with lumbar disc herniation who were referred to Loghman Hakim Hospital for surgery randomly in two groups after signing consent. After surgical incision and reaching about 1 cc of cerebrospinal fluid, the insulin needle remains in place in the dexmedetomidine group and the syringe is removed. With another syringe Dexmedetomidine is injected into the intrathecal space. Finally, 1 cc of cerebrospinal fluid is taken again. But in the control group, the needle is removed. Then, the sample factors will be measured by ELISA in both groups at the beginning and end of surgery and their results will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60; No history of taking anti-inflammatory drugs two weeks before surgery; Lack of AIDS and immunosuppressive diseases. Exclusion criteria: GCS reduction for a reason other than stroke; Change in the type of surgery according to the surgeon's opinion; History of systemic diseases such as diabetes

Intervention groups

Intervention group: After surgical incision a spinal cord fluid sample of 1 cc is taken from the site of surgery, the needle stays in place and the syringe is removed and with another syringe Dexmedetomidine is injected intrathecally. Control group: After surgical incision a spinal cord fluid sample of 1 cc is taken from the site of

surgery. And the needle comes out. At the end, 1 cc of cerebrospinal fluid is again taken from both groups.

Main outcome variables

Bax/Bcl-2 and caspase-3 apoptotic factor levels in cerebrospinal fluid after initiation and at the end of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N1**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Sona Zare

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01
Expected recruitment end date
 2021-08-23, 1400/06/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Evaluating the effect of administration of intrathecal Dexmedetomidine on the Spinal Cord Mori levels of apoptotic factors in patients scheduled for lumbar disc surgery

Public title
 effect of administration of intrathecal Dexmedetomidine on the Spinal Cord Mori

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 No history of taking anti-inflammatory drugs two weeks before surgery Lack of AIDS and immunosuppressive diseases
Exclusion criteria:
 GCS reduction for a reason other than stroke Change in the type of surgery according to the surgeon's opinion History of systemic diseases such as diabetes mellitus, renal failure and chronic pulmonary heart disease

Age
 From **20 years** old to **60 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
 Patients included in the study will be randomly divided into control and Dexmedetomidine groups based on random number table. In this way, we put a set of numbers in a completely random order without any pattern or order, set the table numbers to read from above. For intervention group we consider even numbers and for control group we consider individual numbers. Then we place one of the numbers up and down, register the number and assign it to one of the intervention or control groups.

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Yaman Street, Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-07, 1398/02/17

Ethics committee reference number

IR.SBMU.MSP.REC.1398.098

Health conditions studied

1

Description of health condition studied

Lumbar disc herniation

ICD-10 code

M51

ICD-10 code description

Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders

Primary outcomes

1

Description

The level of Bax / Bcl-2 → apoptotic factor in cerebrospinal fluid in dexmedetomidine and placebo group

Timepoint

After surgery and at the end of surgery

Method of measurement

Study of cerebrospinal fluid in dexmedetomidine and placebo group by ELISA

2

Description

Numering Rating Scale (NRS) Pain score in dexmedetomidine and placebo group

Timepoint

Before anesthesia and in recovery

Method of measurement

NRS scoring system

3

Description

The level of caspase-3 apoptotic factor in cerebrospinal fluid in dexmedetomidine and placebo group

Timepoint

After surgery and at the end of surgery

Method of measurement

Study of cerebrospinal fluid in dexmedetomidine and placebo group by ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgical incision a spinal cord fluid sample of 1 cc is taken from the site of surgery, the needle stays in place and the syringe is removed and with another syringe Dexmedetomidine is injected intrathecally. Finally, 1 cc of cerebrospinal fluid is taken again.

Category

Treatment - Drugs

2

Description

Control group: After surgical incision a spinal cord fluid sample of 1 cc is taken from the site of surgery And the needle comes out. Finally, 1 cc of cerebrospinal fluid is taken again.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hospital

Full name of responsible person

Seyed Sam Hosseinasab

Street address

Loghman Hospital, Makhsoos St, Kamali St, Kargar Ave,

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sam.hn617@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences , Loghman Hospital

Full name of responsible person

Alireza Salimi

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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

Vice chancellor for research, Shahid Beheshti University of Medical Sciences , Loghman Hospital

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Sam Hosseinasab

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable