Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 lll 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 Hosseininasab
Street address
Loghman Hospital, Makhsous St, Kamali St, Kargar Ave,
City
Tehran
Province
Tehran
Postal code
13336-31151
Phone
+98 21 5542 4040
Fax
+98 21 5542 4040
Email
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
Street address
Loghman Hospital, Makhsous St, Kamali St, Kargar Ave,
City
Tehran
Province
Tehran
Postal code
13336-31151
Phone
+98 21 5542 4040
Fax
+98 21 5542 4040
Email
sam.hn167@gmail.com
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 Hosseininasab
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Loghman Hospital, Makhsous St, Kamali St, Kargar Ave
City

Tehran
Province
Tehran
Postal code
13336-31151
Phone
+98 21 2221 5558
Fax
+98 21 5542 4040
Email
sam.hn617@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farhad Safari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Loghman Hospital, Makhsous St, Kamali St, Kargar Ave
City
Tehran
Province
Tehran
Postal code
13336-31151
Phone
+98 21 5542 4040
Fax
+98 21 5542 4040
Email
sam.hn617@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Skin and stem cell research center, Tehran university of medical sciences,
Full name of responsible person
Sona Zare
Position
Researcher
Latest degree
Specialist
Other areas of specialty/work
Medical Biology
Street address
No 4, Maryam Alley, Kamraniyeh street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1937957511
Phone
+98 21 2220 1710
Fax
+98 21 2220 1710
Email
sonazarebio@gmail.com

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