

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between the effect of Dexmedetomidine, Neostigmine, and Ketamine coadministered with bupivacaine 0.5% in epidural administration on decreasing of fibrosis after laminectomy

Protocol summary

Study aim

Comparison between effect of dexmedetomidine, neostigmine and ketamine coadministered with bupivacaine 0.5% in epidural administration on decreasing of fibrosis after laminectomy

Design

phase two clinical trial with parallel groups, double blinded, randomised on 81 patients. for randomisation the rand function of excel software was used

Settings and conduct

epidural injection of each group drugs during the laminectomy surgery by the surgeon in valiasr hospital, arak ,iran. all patients who participate in the trial, the surgeon, the data analysor and the trial responsible intern were blind.

Participants/Inclusion and exclusion criteria

inclusion criteria: all patients candidate for laminectomy surgery all patients with informed consent to participate in the trial all patients with range of age between 25 to 70 years old all patients with anesthetic ASA class I or II
exclusion criteria: all patients out of range of age between 25 to 70 years old all patients who were not candidate for laminectomy surgery all patients with sensitivity to ketamin, neostigmine and dexmedetomidine all patients with anesthetic ASA class more than II all female patients in pregnancy or lactation period all patients with uncontrolled psychological disorders

Intervention groups

dexmedetomidine group: epidural injection with bupivacaine 0.5% ketamin group: epidural injection with bupivacaine 0.5% neostigmine group : epidural injection with bupivacaine 0.5%

Main outcome variables

Mean pain score of patients the mean value of thickness of fibrosis due to laminectomy in MRI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181212041947N1**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Zoha Khademi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3223 0788

Email address

z.khademi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of Dexmedetomidine, Neostigmine, and Ketamine coadministered with bupivacaine 0.5% in epidural administration on decreasing of fibrosis after laminectomy

Public title

effect of Dexmedetomidine, Neostigmin and Ketamin on fibrosis of laminectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients candidate for Laminectomy surgery All patients with informed consent to participate in the trial All patients with range of age between 25 to 70 years old All patients with Anesthetic ASA class I or II

Exclusion criteria:

All patients out of range of age between 25 to 70 years old All patients who were not candidate for Laminectomy surgery All patients with Sensitivity to Dexmedetomidine, Neostigmin and Ketamin All patients with ASA class more than II (III, IV) All female patients in pregnancy or lactation period All patients with uncontrolled psychological disorders

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in 3 groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is clinical trial. Outcome evaluator and analyzer and participant are blind (double blind). Outcome evaluator and analyzer and participant don't aware from grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2018-10-21, 1397/07/29

Ethics committee reference number

IR.ARAKMU.REC.1397.188

Health conditions studied

1

Description of health condition studied

Laminectomy surgery

ICD-10 code

M96.1

ICD-10 code description

Postlaminectomy syndrome, not elsewhere classified

Primary outcomes

1

Description

Mean value of thickness of fibrosis due to laminectomy

Timepoint

3 months after surgery

Method of measurement

Milimeters

2

Description

Pain

Timepoint

2, 6, 12 hours after surgery

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: We inject 0.3 milligram in kilogram of ketamine (volume of which is increased to 3 millilitre), is added to 75 mg of Marcaine 0.25 percent.

Category

Treatment - Drugs

2

Description

Intervention group2: We inject 2/5 milligram of Neostigmine (volume of which is increased to 3 millilitre), is added to 75 mg of Marcaine 0.25 percent.

Category

Treatment - Drugs

3

Description

Intervention group3: We inject 1 micro gram in kilogram of Dexmedetomidin (volume of which is increased to 3 millilitre), is added to 75 mg of Marcaine 0.25 percent.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Alireza Kamali

Street address

Valiasr hospital, Valiasr square

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Markazi

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Phone

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Email

alikamaliir@yahoo.vom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Research Center, Payambar Azam Complex, Basij

square, Sardasht, Arak

City

Arak

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Postal code

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Ali Nazemi Rafie

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

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

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 we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr alireza Kamali

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

They have to write letters to the professors and the university.

Comments

none

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

Arak University of Medical Sciences

Full name of responsible person

Zoha Khademi

Position

Medicine student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

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