Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparison Between Preincisional and Intraoperative Lidocaine Infiltration and Postincisional's surgical Pain in patients undergo Discectomy surgery

Protocol summary

Study aim
comparison of effect of local injection of Lidocaine 2% before and after incision on surgical site pain in patient undergo Lumbar Discectomy

Design
clinical trial with Control group, with parallel group, single-blinded and without randomization

Settings and conduct
interventions is done in Imam Ali (pbuh) hospital located in Bojnurd. patients is divided between two intervention groups and a control group. In first intervention group local analgesic injection will be made before skin incision. In second intervention group local analgesic injection will be made before skin incision. in control receive routine care without any local analgesic injection. patients and care takers dont have any information about groups allocation.

Participants/Inclusion and exclusion criteria
inclusion criteria: decision of surgical treatment for lumbar discopathy, no history of spinal cord surgery, no history of liver, Kidney and Thyroid diseases, weight between 50 to 80 kilograms, no history of addiction
exclusion criteria: Discectomy surgery time lasted over 1 hour, Post anesthesia recovery time lasted over 45 minutes

Intervention groups
First intervention group an injection with Lidocaine 2%, 4 mg per kg (diluted with distilled water to make 30 ml solution) before 5 minutes before skin incision will be made. injection will be made in the muscles of Lumbar Discectomy (per-cutaneous injection in 12, 3, 6 and 9 o'clock positions). In second intervention group an injection with Lidocaine 2%, 4 mg per kg (diluted with distilled water to make 30 ml solution) after 5 minutes after skin incision will be made. injection will be made in the muscles of Lumbar Discectomy (per-cutaneous injection in 12, 3, 6 and 9 o'clock positions). control group don't have any injection and they will receive routine care.

Main outcome variables
postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150930024277N3**
Registration date: **2020-02-17, 1398/11/28**
Registration timing: **retrospective**

Last update: **2020-02-17, 1398/11/28**
Update count: **0**

Registration date
2020-02-17, 1398/11/28

Registrant information

Name
Mehdi Pakbaz

Name of organization / entity

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Iran (Islamic Republic of)

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+98 58 3229 7096

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison Between Preincisional and Intraoperative Lidocaine Infiltration and Postincisional's surgical Pain in patients undergo Discectomy surgery

Public title

Effect of local Lidocaine on Discectomy postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients undergo Lumbar Discectomy patients weight between 50 to 80 Kilograms

Exclusion criteria:

History of spinal cord surgery Liver, Kidney and Thyroid diseases History of addiction

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and the Data Analyzer are Blind to the Study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

Street address

Dolat Blvd.

City

Bojnurd

Province

North Khorasan

Postal code

7487794149

Approval date

2019-06-11, 1398/03/21

Ethics committee reference number

IR.NKUMS.REC.1397.031

Health conditions studied

1

Description of health condition studied

herniated disk

ICD-10 code

M51.06

ICD-10 code description

Intervertebral disc disorders with myelopathy, lumbar region

Primary outcomes

1

Description

score of visual analogue scale

Timepoint

immediately, every hour for 4 hours and every 4 hours for 24 hours postoperatively.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: an injection with Lidocaine 2%, 4 mg per kg (diluted with distilled water to make 30 ml solution) before incision is made. 5 minutes before skin incision, injection is made in the muscles of place of Lumbar Discectomy (per-cutaneous injection in 12, 3, 6 and 9 o'clock positions)

Category

Treatment - Drugs

2

Description

Intervention group: an injection with Lidocaine 2%, 4 mg per kg (diluted with distilled water to make 30 ml solution) after incision is made. 5 minutes after skin incision, injection is made in the muscles of place of Lumbar Discectomy (per-cutaneous injection in 12, 3, 6

and 9 o'clock positions)

Category

Treatment - Drugs

3

Description

Control group: without any analgesic medicine injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali (pbuh) Hospital - Bojnurd

Full name of responsible person

Sepideh Gholami

Street address

Shahriar street

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9417694735

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Sepideh Gholami

Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of data related to variables will be shared

When the data will become available and for how long
Six months after publish

To whom data/document is available
Academic institutions

Under which criteria data/document could be used
Be part of an academic institution

From where data/document is obtainable
Contact Mrs. Sepideh Gholami by Email: sepidgholami1368@gmail.com

What processes are involved for a request to access data/document
proof of academic affliation

Comments