

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of intraoperative epidural dexamethasone and bupivacaine in reduction of pain and disability following lumbar discectomy

Protocol summary

Study aim

Aim was evaluation efficacy of intraoperative epidural dexamethasone and bupivacaine in reduction of pain and disability following lumbar discectomy.

Design

Randomized clinical trial with intervention and control groups; Double blind; Simple blocked randomized; 42 patients.

Settings and conduct

The patients are visited in valiasr hospital of arak .Patient with diagnose of unilateral single level lumbar disc herniation will condidate for surgery.42 patients in two groups are studied. for control group are used plasebo and for intervention group are used combination of dexamethason and bupivacain

Participants/Inclusion and exclusion criteria

Unilateral single level lumbar disc herniation

Intervention groups

The patients are studied in two groups.in intervention group combination of dexamethasone and bupivacain are used and for control group plasebo are used.

Main outcome variables

Low back pain, lower extremities and severe disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201003048906N1**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **retrospective**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

Registration date

2021-03-01, 1399/12/11

Registrant information

Name

Reza Saebirad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4465 6335

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saebiradreza@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of intraoperative epidural dexamethasone and bupivacaine in reduction of pain and disability following lumbar discectomy

Public title

effect of dexamethasone and bupivacaine in reduction of pain and disability after discectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient with unilateral single level disc herniation

Exclusion criteria:

Previous same level surgery Multilevel disc herniation
Spine instability Qauda equina syndrome Spinal kyphosis

and scoliosis Spinal modic change and infection

Age

From **17 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the sample, they are randomly divided into two groups of intervention and control. In this study, individuals were assigned to two groups using permutation block method. In this method, A represents the individual receiving the intervention and B represents the individual in the control group. Considering the quadruple block; they were classified into AABB, ABAB, ABBA, BAAB BBAA and BABA permutations and by randomly selection from permutation patients were classified.

Blinding (investigator's opinion)

Double blinded

Blinding description

In double blinding process patients are informed about use of medication which is not harmful. This medication maybe reduces pain after surgery. At the end of surgery the person who was selected previously prepare medication. The medication can be placebo or combination of dexamethason and bupivacain. Surgeon is not inform about kind of medication. Every patient and medication used for him/her are specified with same number. for example patient: num 8 and medication: num 8

Placebo

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 Science

Street address

No. 3, Shaghayegh Ave., Jahanpanah Blvd.

City

Arak

Province

Markazi

Postal code

38149-5-7558

Approval date

2020-09-06, 1399/06/16

Ethics committee reference number

IR.ARAKMU.REC.1399.185

Health conditions studied

1

Description of health condition studied

Lumbar disc herniation

ICD-10 code

M51.36

ICD-10 code description

Other intervertebral disc degeneration, lumbar region

Primary outcomes

1

Description

Lower limb and back pain

Timepoint

Preoperation and 3,6,12, and 24 hours postoperation

Method of measurement

Visual Analoge Scale

2

Description

Disability score

Timepoint

before surgery and 1 and 6 month after surgery

Method of measurement

Oswestry Disability Index

Secondary outcomes

1

Description

Use of opium dose

Timepoint

24 hours after surgery

Method of measurement

Base of milligram

2

Description

Hospitalization period

Timepoint

Period after surgery

Method of measurement

Number of days

Intervention groups

1

Description

Intervention group: Gelfom is soaked with 2cc dexamethason and 4cc bupivacain (0.5 % solution) aplied on hurted root

Category

Treatment - Drugs

2

Description

Control group: Gelfom is soaked with 6cc normal salin on hurted root

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Aidin Shakeri

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Fax

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Arsh Anoshirvani

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3819693345, Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak.

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Web page address

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

Aidin Shakeri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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

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