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

Registrant information
Name
Reza Saebirad
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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 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 informated 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

**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) applied 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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Sponsors / Funding sources

1
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Arak University of Medical Sciences
Full name of responsible person
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3819693345, Vice Chancellor for Research, Arak University of Medical Sciences, Sardasht, Arak.
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Person responsible for general inquiries

Contact
Name of organization / entity
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Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
Street address
Valiasr Square
City

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