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 placebo 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
Recruitment complete

Acronym
IRCT registration information
IRCT registration number: IRCT20201003048906N1
Registration date: 2021-03-01, 1399/12/11
Registration timing: retrospective

Registrant information
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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 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
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No. 3, Shaghayegh Ave., Jahanpanah Blvd.
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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) applied on hurting 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
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Sponsors / Funding sources

1
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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