Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effectiveness of Oxiplex Gel for reduction of pain and associated symptoms following single level lumbar discectomy

Protocol summary

Study aim

To evaluate the effectiveness of Oxiplex Gel in reduction of pain and associated symptoms following single level lumbar discectomy

Design

Two arm parallel group randomized trial with blinded participants , surgeon and outcome assessment , randomization formed with statistical method : site specific and computer-generated in blocks of 4 and 2 , and sample size is 30 in each group

Settings and conduct

Pain and disability after surgery are important problems in spinal surgeries. The aim of this study is to evaluate the effectiveness of Oxiplex Gel gel in reduction of back and leg pain and disability after single level lumbar discectomy. The study population is 60 patients referred to Vali Asr hospital who are candidate for single level lumbar discectomy based on physical examination and radiologic assessment . Next stage, participants fill the ODI (Oswestry Disability Index) questionnaire and informed consent before surgery. We divide patients in receiving gel or receiving placebo groups randomly . Effectiveness of gel will be assessed in 1 , 3 , 6 month after surgery based on ODI parameters.

Participants/Inclusion and exclusion criteria

Inclusion criteria : all adults, age between 18 to 70 years old , with lumbar disk herniation come to Vali Asr hospital who are candidate for open lumbar discectomy surgery for treatment Exclusion criteria : history of previous lumbar surgery , multi level disk herniation

Intervention groups

At the end of open lumbar discectomy and before closure in intervention group the surgical field will be covered with 3 cc of Oxiplex Gel and in control group placebo will be applied to surgical field

Main outcome variables

Pain and disability after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043260N1**
Registration date: **2019-04-25, 1398/02/05**
Registration timing: **retrospective**

Last update: **2019-04-25, 1398/02/05**
Update count: **0**

Registration date

2019-04-25, 1398/02/05

Registrant information

Name

keyhan poorali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3221 5657

Email address

keyhan_poorali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-10-12, 1397/07/20

Trial completion date

2019-04-09, 1398/01/20

Scientific title

Evaluation the effectiveness of Oxiplex Gel for reduction of pain and associated symptoms following single level lumbar discectomy

Public title
Effect of Oxiplex Gel in lumbar disk herniation surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patient with single level lumbar disk herniation
Patients who are candidate for discectomy surgery for treatment based on physical examination and radiologic evaluation
Exclusion criteria:
Patient with multilevel lumbar disk herniation History of previous lumbar surgery
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
<Randomiziation formed with statistical method , site-specific and computer-generated in blocks of 4 and 2 , based on each number, boxes with specific identified number containing Oxiplex Gel or Placebo dedicated
Blinding (investigator's opinion)
Triple blinded
Blinding description
All patient participating , the surgeon and outcome assessment are blind in this study. Boxes in similar size and form with specific identified number which include Oxyplex Gel or the similar placebo will be delivered to the surgeon at the termination of surgery and the surgeon have no information about the type of syringe`s contents when he uses the syringe.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Arak University of Medical Sciences
Street address
No. 7, Faridi Alley ,Rajaei Ave
City
Arak
Province
Markazi
Postal code
3813957517
Approval date
2018-06-17, 1397/03/27
Ethics committee reference number
IR.ARAKMU.REC.1397.088

Health conditions studied

1

Description of health condition studied
Lumbar disc herniation
ICD-10 code
M51.1
ICD-10 code description
Thoracic, thoracolumbar and lumbosacral intervertebral disc disorders with radiculopathy

Primary outcomes

1

Description
Disability index
Timepoint
Before surgery , 1 month , 3 month, 6 month after surgery
Method of measurement
Oswestry Disability Index (ODI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : at the end of open lumbar discectomy surgery and before closure , 3 cc of Oxiplex Gel will be injected to surgery site on dura and nerve roots. Oxiplex Gel (carboxymethylcellulose, polyethylene oxide, and calcium) made in Fzio Med Inc is a clear , absorbable and anti fibrosis agent that it`s safety for human being is approved.
Category
Treatment - Other

2

Description
Control group: at the end of open lumbar discectomy surgery and before closure , 3 cc of placebo will be injected to surgery site on dura and nerve roots.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr hospital
Full name of responsible person
Keyhan Poorali
Street address
Vali Asr Square
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3814957558
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+98 86 3223 1283
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Keyhan_poorali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamad Arjmandzadegan
Street address
Basij Sq , Arak university of medical sciences complex
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Markazi
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3848176341
Phone
+98 86 3417 3639
Fax
+98 86 3417 3645
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mmatinam81@yahoo.com
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
Keyhan Poorali
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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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
All data after unrecognizaton the patients can be shared
When the data will become available and for how long
beginning of accessibility is six month after publication
To whom data/document is available
researchers working at university
Under which criteria data/document could be used
for clinical use
From where data/document is obtainable
My email address (keyhan _poorali @yahoo.com)
What processes are involved for a request to access data/document
About one week to one month after request data file will be send
Comments