

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

<Randomization 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 Oxypex 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 committee of Arak University of Medical Sciences

Street address

No. 7, Faridi Alley ,Rajaei Ave

City

Arak

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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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Email

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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Email

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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Person responsible for updating data**Contact****Name of organization / entity**

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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