Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Determine the effect of Oxiplex gel on pain relief and related symptoms after bilateral lumbar discectomy

Protocol summary

Study aim
Determine the effect of Oxiplex gel on pain relief and associated symptoms after a bilateral lumbar discectomy

Design
The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 30.

Settings and conduct
In this research, all patients referred to the Hazrat Rasoul Akram Hospital, who candidates for a bilateral lumbar diskectomy will be enrolled. Patients will be randomly divided into two groups based on 6 blocks. A total of 60 patients will be examined. Patients and data analyzers will be blind.

Participants/Inclusion and exclusion criteria
All patients referred to Rasoul Akram Hospital, who suffered from lumbar disc herniation, will be enrolled. Inclusion criteria: All patients who will candidates for a bilateral lumbar diskectomy based on clinical signs and imaging, Patients over 18 years old. Exclusion criteria: Patients over 70 years old, Patients corticosterone recipients during the four weeks prior to surgery, Patients with intervertebral hole stenosis

Intervention groups
In the intervention group, patients will receive a 3-cc oxylex gel to cover the site during a discectomy for a single time, and in control group patients do not receive gel treatment during a discectomy.

Main outcome variables
Low back pain, Referral pain from lower back to lower limb, Score of conflict due to the disease and the reduction performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171124037606N1**
Registration date: **2019-01-12, 1397/10/22**
Registration timing: **prospective**

Last update: **2019-01-12, 1397/10/22**
Update count: **0**

Registration date
2019-01-12, 1397/10/22

Registrant information

Name
Alireza Tabibkhooei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-04, 1397/11/15

Expected recruitment end date
2019-07-21, 1398/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determine the effect of Oxiplex gel on pain relief and related symptoms after bilateral lumbar discectomy

Public title
Determine the effect of Oxiplex gel after discectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who will candidates for a bilateral lumbar diskectomy based on clinical signs and imaging Patients over 18 years old

Exclusion criteria:

Patients over 70 years old Patients corticosterone recipients during the four weeks prior to surgery Patients with intervertebral hole stenosis

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**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks with 6 person. In each block, 3 individuals will be in intervention group and 3 will be in control group. A total of 10 blocks will be considered for sample size.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Data will be analyzed by person who is blind to study groups. Patients and Surgeon will also be unaware of the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-12-25, 1396/10/04

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9211255001

Health conditions studied

1

Description of health condition studied

Lumbar disc herniation

ICD-10 code

S33.0

ICD-10 code description

Traumatic rupture of lumbar intervertebral disc

Primary outcomes

1

Description

Low back pain

Timepoint

Preoperatively, the next day after the operation, one month three months and six months after the operation

Method of measurement

From 1 to 10 (Based on numerical scale).

2

Description

Referral pain from lower back to lower limb

Timepoint

Preoperatively, the next day after the operation, one month three months and six months after the operation

Method of measurement

From 1 to 10 (Based on numerical scale).

3

Description

Score of conflict due to the disease and the reduction performance

Timepoint

Preoperatively, the next day after the operation, one month three months and six months after the operation

Method of measurement

From 1 to 10 (Based on numerical scale).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who receive a 3-cc oxylex gel to cover the site during a discectomy for a single time.

Category

Treatment - Drugs

2

Description

Control group: Patients who do not receive gel treatment during a discectomy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Akram hospital

Full name of responsible person

Alireza Tabibkhooei

Street address

Hazrate Rasool hospital, Niyayesh street, Sattarkhan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Feize Allah Ebrahim Nia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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