

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation the safety and effectiveness of Oxiplex Gel for reduction of pain and associated symptoms followingsingle level lumbar discectomy

Protocol summary

2019-04-23, 1398/02/03

Study aim

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

Design

This study is clinical trials and double blind. 60 patients candidate discectomy in valiasr hospital will inter in this study. We will divide the patients to 2 groups.

Settings and conduct

This study is clinical trials and double blind. 60 patients candidate discectomy in valiasr hospital will inter in this study. This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind).Outcome assessor and analyzer not aware from grouping.The person evaluating the outcome is unaware of the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria:18-70 years, Lumbar disc disease

Exclusion criteria:Dissatisfaction

Intervention groups

Patients in the two groups randomly receive Oxiplex gel and the placebo receptor are placed right in the site before closure of the surgical site.

Main outcome variables

Disability- pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N106**

Registration date: **2019-04-23, 1398/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

Registration date

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the safety and effectiveness of Oxiplex Gel for reduction of pain and associated symptoms followingsingle level lumbar discectomy

Public title

Evaluation the safety and effectiveness of Oxiplex Gel for reduction of pain and associated symptoms followingsingle level lumbar discectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-70 years Lumbar disc disease
Exclusion criteria:
Dissatisfaction

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with random number table in division of groups in two groups A and B. Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak
Province
Markazi
Postal code
3814957558
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

ICD-10 code

M51.9

ICD-10 code description

Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder

Primary outcomes

1

Description

Disability

Timepoint

Before intervention, 1, 3 and 6 months after intervention

Method of measurement

Oswestry low back pain disability

2

Description

Pain

Timepoint

Before intervention, 1, 3 and 6 months after intervention

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First group receive Oxiplex gel are placed right in the site before closure of the surgical site.

Category

Treatment - Drugs

2

Description

Control group: Second group receive placebo are placed right in the site before closure of the surgical site.

Category

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Mohsen Dalvandi

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Valiasr Hospital, Valiasr square, Shahid Shirodi street

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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

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

Dr Alireza Mohammadi

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Arak University of Medical Sciences

Full name of responsible person

Dr Mohsen Dalvandi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Keihan Poorali

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resident of neurosurgery

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Dalvandi

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments