

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 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)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### 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

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3417 3645

##### Fax

+98 86 3222 2003

##### Email

dalvandi@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Arjmandzadegan

##### Street address

Vice chancellor for research, Payambar Azam  
Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3814957558

##### Phone

+98 86 3341 3638

##### Email

m.arjmandzadegan@arakmu.ac.ir

##### 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

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

##### City

Arak

##### Province

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##### Postal code

3814957558

##### Phone

+98 86 3222 2003

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##### Email

mohamadi@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Dalvandi

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurosurgery

##### Street address

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##### Email

dalvandi@arakmua.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Keihan Poorali

**Position**

resident of neurosurgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

Complex Payambar azam, Basij square, Sardasht, Arak

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**Province**

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**Postal code**

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**Email**

keyhan\_poorali@yahoo.com

**Web page address**

## 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