

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparative study of quality of life and non surgical and surgical treatment results in patients with lumbar disc herniation

Protocol summary

Study aim

Comparative study of quality of life and non surgical and surgical treatment results in patients with lumbar disc herniation

Design

This study is a non-blind clinical trial. The study population will include all patients referred to the Kermanshah Neurology clinic. A total of 100 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study will be conducted in the Kermanshah Neurology clinic is a non-blinded one. At the beginning of the study, the severity of pain, functional disability, and quality of life of patients for both groups are recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of lumbar disc herniation by a neurosurgeon; About a month has passed since they became ill; No neurological defects including weakness of limbs and sphincter disorder Exclusion criteria: Suffering from other diseases including vertebral and spinal tumors, vertebral fractures, inflammatory diseases, mental illness, and trauma; People with underlying diseases such as orthopedic, heart and respiratory problems; People with lung infection, renal, metabolic disorders, stroke or trauma

Intervention groups

The first intervention group will undergo surgery. The second intervention group receives medical treatments.

Main outcome variables

Quality of life, pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N153**

Registration date: **2020-07-19, 1399/04/29**

Registration timing: **prospective**

Last update: **2020-07-19, 1399/04/29**

Update count: **0**

Registration date

2020-07-19, 1399/04/29

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of quality of life and non surgical and surgical treatment results in patients with lumbar disc herniation

Public title

comparison of quality of life and non surgical and surgical treatment results in patients with lumbar disc herniation		Research Affairs, Kermanshah University of Medical Sciences	
Purpose	Treatment	City	Kermanshah
Inclusion/Exclusion criteria		Province	Kermanshah
Inclusion criteria:	Definitive diagnosis of lumbar disc herniation by a neurosurgeon About a month has passed since they became ill No neurological defects including weakness of limbs and sphincter disorder	Postal code	6715847141
Exclusion criteria:	Suffering from other diseases including vertebral and spinal tumors, vertebral fractures, inflammatory diseases, mental illness and trauma People with underlying diseases such as orthopedic, heart and respiratory problems People with lung infection, renal, metabolic disorders, stroke or trauma	Approval date	2018-10-09, 1397/07/17
		Ethics committee reference number	ir.kums.rec.1397.547
Health conditions studied			
<u>1</u>			
Description of health condition studied		Lumbar disc herniation	
ICD-10 code		M51	
ICD-10 code description		Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders	
Primary outcomes			
<u>1</u>			
Description		Quality of life	
Timepoint		Six weeks, three months and one year after starting treatment	
Method of measurement		Based on Quality of Life Questionnaire (SF36)	
<u>2</u>			
Description		pain intensity	
Timepoint		Six weeks, three months and one year after starting treatment	
Method of measurement		Based on the visual scale of pain (VAS)	
Secondary outcomes			
empty			
Ethics committees			
<u>1</u>			
Ethics committee			
Name of ethics committee		Ethics committee of Kermanshah University of Medical Sciences	
Street address		Building No.2, Shahid Beheshti, Vice Chancellor for	

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Description

The second intervention group receives medical treatments.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of University of Medical Sciences

Full name of responsible person

Azadeh Asgari

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

azadeh.asgari26@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Azadeh Asgari

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

azadeh.asgari26@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Fatahian

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

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+98 83 3427 6306

Email

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Azadeh Asgari

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Phone

+98 83 3427 6306

Email

azadeh.asgari26@yahoo.com

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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments