Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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

Purpose

Treatment

Inclusion/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

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the first intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the second intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

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

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-10-09, 1397/07/17

Ethics committee reference number

ir.kums.rec.1397.547

Health conditions studied

1

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

1

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)

2

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

Intervention groups

1

Description

The first intervention group will undergo surgery

Category

Treatment - Surgery

2

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
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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
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Kermanshah
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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
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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
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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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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