

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

the effect of core stability exercises on the patient's quality of life after lumbar spine surgery

Protocol summary

Study aim

Determining the effect of core stability exercises on the quality of life of patients after lumbar spine surgery

Design

Double-blind randomized clinical trial, simple random sampling method. The sample size was determined using the 95% CI and using the sample size formula ($Z1=1.96$, $Z2=0.84$, $d=0.7$, $S=16.4$) of 64 people.

Settings and conduct

patients who undergo decompression surgery in loghman hakim hospital are included in the study based on random allocation

Participants/Inclusion and exclusion criteria

The population studied in this research includes patients aged 18 to 65 years with lumbar discopathy who are scheduled to undergo decompression surgery

Intervention groups

Patients who visit by a neurosurgeon, if eligible, The information will be collected. the information obtained at the beginning and end of the intervention (on arrival, 1, 3 and 6 months later) is collected as follows. 4 weeks after the operation, the patient is given core stability one exercises. Full exercise is given under the supervision of the person in charge of the treatment and it is explained to the patient that 15 to 20 minutes of exercises should be done at home every day. In case of any problems related to sports or physical problems, the patient can contact a doctor specializing in sports medicine or treatment by phone or other means of communication. three and six months after the surgery, the patient is visited again and he is given level two and three exercises. the patient is evaluated over the phone for daily exercises. In the control group, the sequence of visits is similar to the intervention group, only the type of exercises taught are stretching and strengthening for the abdominal muscles, the muscles of the back of the thigh, and the spine (central stability exercises are not given).

Main outcome variables

Quality of life (completed with the WHOQOL-BREF

questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220924056027N1**

Registration date: **2023-04-26, 1402/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-26, 1402/02/06**

Update count: **0**

Registration date

2023-04-26, 1402/02/06

Registrant information

Name

omidvar rezaei mirghaed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5102 5596

Email address

dromidvarrezaee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2023-04-30, 1402/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	after the intervention are done by a person who does not know about the presence of patients in the groups
Scientific title the effect of core stability exercises on the patient's quality of life after lumbar spine surgery	Placebo Not used
Public title the effect of core stability exercises on the patient's quality of life after lumbar spine surgery	Assignment Parallel
Purpose Treatment	Other design features
Inclusion/Exclusion criteria Inclusion criteria: -Patients (male and female) aged 18 to 65 with lumbar discopathy who must undergo decompression surgery - Having a referral letter from a neurosurgeon -Full consent of the patient to participate in the research - Mental state of pain - Absence of acute traumatic injury in the spine - Absence of injury in the spine - Absence of malignancy Exclusion criteria: -Suffering from neuro-muscular diseases -suffering from a malignant tumor -suffering from chronic diseases or other known conditions that affect the research - participating in physical therapy or exercise therapy programs during the last three months - unwillingness to participate in the research plan -Failure to complete treatment plans -receiving any treatment other than the treatment prescribed in this research plan	Secondary Ids empty
Age From 18 years old to 65 years old	Ethics committees 1 Ethics committee Name of ethics committee Organizational Committee of Ethics in Biomedical Research of Shahid Beheshti University of Medical S
Gender Both	Street address loghman hakim hospital , makhsos St , south kargar Ave
Phase N/A	City tehran
Groups that have been masked • Participant • Outcome assessor • Data analyser	Province Tehran
Sample size Target sample size: 64	Postal code 1333635445
Randomization (investigator's opinion) Randomized	Approval date 2022-07-24, 1401/05/02
Randomization description The sequence of random allocation was determined by a member of the research team not involved in the selection of samples and was used in sealed sealed envelopes in order of numbering to hide the allocation. Exercise therapy group patients should visit the clinic on even days and control group patients on odd days.	Ethics committee reference number IR.SBMU.RETECH.REC.1401.269
Blinding (investigator's opinion) Double blinded	Health conditions studied 1 Description of health condition studied lumbar herniation discopathy
Blinding description The patient receives the type of intervention in a sealed envelope that is coded. Coding is done by one of the colleagues, and the patient does not know in which exercise therapy group he is placed, and the quality of life evaluator does not know about the treatment received by the patient.The patients of the exercise therapy group visit the clinic on even days and the control group on odd days. Also, evaluations before and	ICD-10 code M51.8
	ICD-10 code description Other thoracic, thoracolumbar and lumbosacral intervertebral disc disorders
	Primary outcomes 1 Description quality of life
	Timepoint Before, 1, 3 and 6 months after surgery
	Method of measurement WHOQOL-BREF questionnaire
	Secondary outcomes empty

Intervention groups

1

Description

In the intervention group, patients receive core stability exercises stage one and two. exercise training is given under the supervision of the person in charge of the treatment and explained to the patient that 15 to 20 minutes of exercises should be done at home every day. Phase one of core stability exercises begins one month after surgery and is performed daily for two months. In the third month, the second stage of core stability are performed that continues for sixth month.

Category

Rehabilitation

2

Description

Control group: In the control group, the usual stretching exercises of the lower limbs and spine are taught, which should be done daily for 15 to 20 minutes. These training are given under the supervision of the person in charge of treatment, and the duration of doing sports, like the intervention group, should continue for 6 months.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

omidvar rezaeimirghaed

Street address

Loghman Hakim Hospital, Makhsos St, South Kargar Ave

City

tehran

Province

Tehran

Postal code

1333635443

Phone

+98 21 5102 5000

Email

dromidvarrezaee@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 29901

Email

azarghi@yahoo.com

Web page address

https://isid.research.ac.ir/Afshin_Zarghi

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

omidvar rezaeimirghaed

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

loghman hakim hospital, makhsos St, kargar Ave

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Person responsible for scientific

inquiries

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Person responsible for updating data

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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

SPSS file data can be shared

When the data will become available and for how long

After printing the article

To whom data/document is available

RESEARCHERS

Under which criteria data/document could be used

Secondary studies

From where data/document is obtainable

Correspond by email

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

Send after receiving email

Comments