Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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

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

Purpose
Treatment

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

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

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.

Blinding (investigator's opinion)
Double blinded

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 after the intervention are done by a person who does not know about the presence of patients in the groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational Committee of Ethics in Biomedical Research of Shahid Beheshti University of Medical S

Street address
loghman hakim hospital , makhsos St , south kargar Ave

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Province
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1333635445

Approval date
2022-07-24, 1401/05/02

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.269

Health conditions studied

1

Description of health condition studied
lumbar herniation discopathy

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

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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

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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

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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