Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation effect of Lumbar-sacral recovery machine on severity of sign and symptom of patients with discopathy

Protocol summary

Study aim
Determining the effect of back and knee recovery device on the severity of symptoms of patients with discopathy

Design
The clinical trial will have two groups, with a control group, single blind, randomized on 74 patients.

Settings and conduct
The research environment includes orthopedic clinics affiliated to Tehran University of Medical Sciences, orthopedic specialist doctors' office and health and wellness clinic, where treatment is performed with a lumbar stretching device. The method of use is that the person is slowly placed on the device in a chair position and after the initial settings such as sitting height and other controllable items, the chair is slowly turned into a bed and after fixing the upper body and lower body. Various recovery programs that include various types of stretching are implemented.The number of intervention sessions three times a week is between 30 and 35 sessions at most, and this number of sessions varies depending on individual differences and structures, including lifestyle, mental and psychological state, physical and stress. Single blinding will be done for statistical analyst.Groups name enter spss as 1 and 2 and then file will be sent for statistical person.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Age between 18 and 60 years - Diagnosis of Lumbar and Sacral Grade 1 and 2 discopathy according to the doctor's diagnosis Exclusion criteria: - Worsening of the disease and progression to grade 3 and 4 discopathy - Finding any possible complications caused by using the device

Intervention groups
The test group, the use of knee back recovery device in patients with discopathy of lumbar and sacral grade 1 and 2 Control group, routine care

Main outcome variables
pain, Activity daily living, comfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191027045257N3**
Registration date: **2023-04-09, 1402/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-09, 1402/01/20**
Update count: **0**

Registration date
2023-04-09, 1402/01/20

Registrant information

Name
Pegah Matourypour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-16, 1401/12/25

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigation effect of Lumbar-sacral recovery machine on severity of sign and symptom of patients with discopathy

Public title
Investigation effect of Lumbar-sacral recovery machine on sign and symptom of patients with discopathy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 60 years old Having the desire to use the back and knee recovery device along with other prescription treatments of your doctor Diagnosis of lumbar discopathy and sacral grade 1 and 2 to the diagnosis of the doctor
Exclusion criteria:
Existing other disease or abnormalities in the spine
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of samples will be done at the individual level through sealed envelopes from among those who refer to the research environments (Clinics of Sina and Imam hospitals). The randomization method will be simple. The random allocation of samples will be in such a way that sealed envelopes will be prepared according to the number of samples (37 envelopes for the control group and 37 for the intervention group). Patients referring to the mentioned clinics who meet the entry criteria are asked to choose one item from among 74 envelopes to determine their group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding will be for the statistical analyzer so that the data will be entered into spss software by the other person and the experimental and control groups will be marked with numbers 1 and 2, then the statistical analyzer will perform the relevant tests on the data.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tohid square- Nursing & Midwifery faculty
City
Tehran
Province
Tehran
Postal code
7887990
Approval date
2023-02-18, 1401/11/29
Ethics committee reference number
IR.TUMS.FNM.REC.1401.178

Health conditions studied

1

Description of health condition studied
Discopathy
ICD-10 code
M51.9
ICD-10 code description
Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder

Primary outcomes

1

Description
pain
Timepoint
Before intervention and at the end session of intervention
Method of measurement
Visual Analogue scale (VAS)

Secondary outcomes

1

Description
Activity Daily Living
Timepoint
Before intervention and at the end session of intervention
Method of measurement
Katz- Activity Daily Living

Intervention groups

1

Description
Intervention group: The intended intervention is the use of a back and knee recovery device (Kemarasa). The intervention method is that the person is slowly placed on the device in a chair position and after the initial settings such as sitting height and other controllable items, the person slowly turns from the chair position into a bed position and after fixing the upper body and For the lower body, a different recovery program is implemented that includes various types of stretching. The tension applied to the vertebral column in terms of the type of design and the degree of freedom of the tension angle reduces the injury to a minimum, even for high-risk people. The number of intervention sessions three times a week is between 30 and 35 sessions, and this number of sessions varies depending on individual differences and structures, including lifestyle, mental and psychological state, physical and stress. The intervention is performed by a trained technician.

Category
Rehabilitation

2

Description
Control group: In the control group, the demographic information form and visual scale of pain intensity and comfort and katz-ADL activities of daily living will be completed at the beginning of the study and also at the end of the study.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Masoumeh Zakerimoghadam
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The publication of the article and the final report of the plan will be done. There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable