

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4126

Email address

matourypour@yahoo.com

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 Zakerimoghdam

Street address

Tohid square- Mirkhani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Zakerimoghdam

Position

Member of faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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