Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of physiotherapy , hydrotherapy and combination methods on pain and Functional Disability in patients with Chronic Low Back Pain due to Lumbar Disc Herniation

Protocol summary

Study aim
Comparison of the effect of three methods of physiotherapy, hydrotherapy and combination on pain and functional disability in patients with chronic low back due to Lumbar Disc Herniation

Design
A Single blind randomized clinical trial with parallel groups and an eight-week follow-up. The sample size was obtained according to the results of similar studies and using G power software; 20 people in each group.

Settings and conduct
According to the inclusion criteria, patients are called to the physiotherapy clinic by referring a doctor and then are randomly assigned to one of the groups. This is a Single blind clinical study in which the evaluator does not know which group the patients belong to.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men with chronic low back pain due to lumbar disc herniation with a history of pain of more than three months; Age range 25 to 50 years; Body mass index between 20-25; Having moderate pain means pain of at least 4 and at most 7 with the characteristic of visual pain scale. Conditions of absence: history of lumbar surgery; Use of special medications and painkillers; History of underlying diseases such as heart disease, respiratory disease, diabetes and etc.

Intervention groups
Intervention group 1: using electrotherapy and exercise therapy for eight weeks and three times a week.Intervention group 2: Performing exercises in water with a temperature of 32 degrees Celsius for eight weeks and three times a week. Intervention group 3: use of electrotherapy and exercise therapy in the first four weeks and three times a week and use of hydrotherapy in the second four weeks.Control group:This group is told to take an absolute break at this time

Main outcome variables
Pain, functional disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200302046675N1**
Registration date: **2020-11-05, 1399/08/15**
Registration timing: **prospective**

Last update: **2020-11-05, 1399/08/15**
Update count: **0**

Registration date
2020-11-05, 1399/08/15

Registrant information

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The university of shams

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-10, 1399/08/20

Expected recruitment end date
2020-12-10, 1399/09/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of physiotherapy , hydrotherapy and combination methods on pain and Functional Disability in patients with Chronic Low Back Pain due to Lumbar Disc Herniation

Public title

The effect of physiotherapy , hydrotherapy and combination methods on patients with Lumbar Disc Herniation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body Mass Index between 20-25 Having moderate pain means a minimum of 4 and a maximum of 7 with a Visual Analouge Scale index Men with chronic low back pain caused by a lumbar disc herniation with a history of pain of more than three months

Exclusion criteria:

History of lumbar surgery Use of special medications and painkillers History of underlying diseases such as heart disease, respiratory disease, diabetes, etc.

Age

From **25 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization in that a number of cards are considered by the researcher as the first group (physiotherapy) and the same number of cards for other groups (hydrotherapy, combination and control group); Then, by merging the cards together, a card is taken out and its allocation is recorded and returned to the other cards. The cards are then merged again and another card is removed. Also, the number of cards is not necessarily equal to the total number of samples.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a Single blind clinical trial in which a expert physiotherapist will perform intervention and other physiotherapists will perform the Assessment. As a result, the Assessor will not know which group the patient belongs to.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of babol University of Medical Sciences

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University of Medical Sciences,Ganj Afrooz St,Babol,Mazandaran

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Postal code

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Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

IR.MUBABOL.REC.1399.228

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

Pain

Timepoint

Before treatment, the eighth week of treatment

Method of measurement

Visual analog scale

2

Description

Functional disability

Timepoint

Before treatment, the eighth week of treatment

Method of measurement

Oswestry Disability Questionnaire (ODQ)

Secondary outcomes

empty

Intervention groups

1

Description
intervention group 1 : The physiotherapy protocol includes TENS method and exercise therapy. TENS method performed with a multistim device model 735M made by Novin company and exercise therapy is performed in accordance with the evaluation and prescribing instructions of the American School of Sports Medicine. This intervention is performed for 8 weeks and 3 times a week for 60 minutes each time.
Category
Treatment - Devices

2

Description
intervention group 2 : Hydrotherapy, These exercises were performed in water with a depth of 1 to 2 meters and a temperature of 28 to 32 degrees Celsius. Exercises three times a week for 8 weeks, each time for 60 minutes.
Category
Treatment - Devices

3

Description
Intervention group 3 : combination group , Treatment in this group was a combination of physiotherapy and hydrotherapy. Thus, in the first month, three sessions per week and 60 minutes per session, physiotherapy and in the second month, three sessions per week and each session 60 minutes, hydrotherapy is performed.
Category
Treatment - Devices

4

Description
Control group : Patients are told not to use any treatment model for eight weeks and to rest completely.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy Iman
Full name of responsible person
Mohammad Shams Tabar Kami
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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
Babol 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
The University of Shams
Full name of responsible person
Mohammad Shams Tabar Kami
Position

University Student

Latest degree

Master

Other areas of specialty/work

Sport Pathology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

If needed by researchers and their request, the raw data of research and it's analysis will be available to researchers

When the data will become available and for how long

After the publication of articles resulting from the research

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data are available only to other researchers to study and evaluate treatment outcomes.

From where data/document is obtainable

By sending an email to the corresponding author

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

Send an email and the request will be answered shortly after review.

Comments