

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Effect of 4 weeks comprehensive PREPARE aquatic therapy before Laminectomy and 8 weeks post operation for functional status, foot pressure distribution and EMG activation of core muscle in women with chronic low back pain

Protocol summary

Study aim

The aim of this study is check of Effects of four weeks comprehensive PREPARE aquatic therapy before Laminectomy on functional status, foot pressure distribution and EMG activation of core muscle in chronic low back pain patients.

Design

This study is a randomized clinical trial with parallel group trial and single blinded outcome assessment. Based on G*POWER software 30 patients as sample size were determined and randomly divided into two group of experimental and control group.

Settings and conduct

This study was carried out at Besat Hospital of Hamedan. Patient of excremental group received rehabilitation program 4 weeks before and 8 weeks after surgery while control group only 8 weeks program after surgery. The program designed in different days and patients were unaware of other participants.

Participants/Inclusion and exclusion criteria

Adult between 30 to 60 years old Chronic low back pain, with or without radiculopathy Diagnosis of Herniated disc between L5 and S1 by a neurosurgeon with paraclinical procedures such as MRI No history of lumbar spine surgery / tumors / fractures / pregnancy Exclusion criteria Any history of lumbar vertebral fractures, types of tumors, scoliosis, previous spine surgery and severe postural deformities Neuromuscular diseases like MS Rheumatoid Arthritis Osteoporosis

Intervention groups

women with chronic low back pain that candidate Laminectomy divided tow groups 15 person as control and intervention groups. intervention group receive 4 weeks prehabilitation aquatic therapy before Laminectomy. then post operation 8 weeks posthabilitation. control group receive 8 weeks post

surgery rehabilitation .

Main outcome variables

in this study functional status, foot pressure distribution and EMG activation of core muscle in chronic low back pain evaluate.

General information

Reason for update

Acronym

PREPARE

IRCT registration information

IRCT registration number: **IRCT20200323046838N1**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Azam Bashiri

Name of organization / entity

The University of Kharazmi, international nuit

Country

Iran (Islamic Republic of)

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mary.bashiri53@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-25, 1399/01/06

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 4 weeks comprehensive PREPARE aquatic therapy before Laminectomy and 8 weeks post operation for functional status, foot pressure distribution and EMG activation of core muscle in women with chronic low back pain

Public title

Effect of 4 weeks prehabilitation aquatic therapy to women with chronic low back pain how candidate Laminectomy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult with 30 - 60 years old Having chronic low back pain with or with out radiculopathy herniation of L4, L5, S1 disk by MRI BMI within 22 - 32 no surgical history on spinal column , Having Tumor or malignancy ,scoliosis, fractures and pregnancy Having mental health consent for participation to study

Exclusion criteria:

having surgical history on spinal column having scoliosis BMI> 32 having malignancy and tumor having seveal heart disease opiate addiction having MS having osteoprosis

AgeFrom **30 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

By using random number table participants were divided in to control and intervention group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Clinical care staff or trainer staff were unaware of group division.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethical committee of hammedan university of medical sciences

Street address

No 54, ferdosi Alley, Morvarid Avenue, Sadaf Street, Hamedan city , Iran

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Postal code

6515787498

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.UMSHA.REC.1397.993

Health conditions studied**1****Description of health condition studied**

patient with chronic low back pain candidate Laminectomy

ICD-10 code

M54.16

ICD-10 code description

Radiculopathy, lumbar region

Primary outcomes**1****Description**

pain.

Timepoint

At the baseline (before surgery) and after 8 weeks rehabilitation.

Method of measurement

To assess pain the VAS ruler will be used.

2**Description**

Foot pressure distribution

Timepoint

At the baseline (before surgery) and after 8 weeks rehabilitation.

Method of measurement

Foot scan will be used to evaluate foot pressure

distribution.

3

Description

Electrical activity of muscles

Timepoint

At the baseline (before surgery) and after 8 weeks rehabilitation.

Method of measurement

By using Electromyography

Secondary outcomes

1

Description

functional status

Timepoint

At the baseline and end of rehabilitation program.

Method of measurement

By using Osvestry Questionnaire Index,

Intervention groups

1

Description

Intervention group or prehabilitation group participate in aquatic training 4 week before and 8 week after surgery. Aquatic exercise training for intervention group or prehabilitation group includes 3 session per week for a 4 week which each session includes 10 minutes warm up, 40 minutes resistant training in water and 10 minutes cooling down before surgery. The same program for 8 weeks including 3 session per week which each session includes 10 minutes warm up, 40 minutes resistant training in water and 10 minutes cooling down will be done by intervention group after surgery.

Category

Rehabilitation

2

Description

Control group: The control group participate only in 8 week aquatic training includes 3 session per week which each session includes 10 minutes warm up, 40 minutes resistant training in water and 10 minutes cooling down as routine rehabilitation program after surgery.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital of Hamedan

Full name of responsible person

Azam Bashiri

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Ayatollah Motahari BLV, Resalat Square, Hamedan ,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The international unit of University of Kharazmy of Teheran

Full name of responsible person

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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

The international unit of University of Kharazmy of Teheran

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

International Unit Of Kharazmi University Of Teheran

Full name of responsible person

Azam Bashiri

Position

student of PHD course

Latest degree

Master

Other areas of specialty/work

sport science

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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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

all of the data and all kind of ways for data collection and
statistical analysis publish in this study

When the data will become available and for how long

6 month after publish

To whom data/document is available

for researchers of university or science academy

Under which criteria data/document could be used

to use for else research

From where data/document is obtainable

with email: mary.bashiri53@gmail.com

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

with send email and announce me aim of request within
2 working day.

Comments