

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of radial extracorporeal shock wave therapy addition on routine physiotherapy treatment on the balance& pain & disability of patients with chronic non-specific low back pain caused by gluteal muscle trigger points

Protocol summary

Study aim

Effects of Shockwave Addition on Physiotherapy Treatment on Balance, Pain and Disability in Patients with Chronic Nonspecific Low Back Pain Due to Gluteal Muscle Trigger Point in Intervention and Control Groups

Design

Control group two days of weekly physiotherapy routine treatment for 5 weeks, including a hot water bag for 20 minutes and an Ultrasound with a Frequency of 1 MHz for 5 minutes and TENS 5 Hz for 15 minutes with the shockwave off and the other group receive routine physiotherapy treatment with the shockwave. In addition to routine shock therapy, people in the intervention group also receive shockwave physiotherapy, in which the patient is placed in a prone position and the shockwave applicator is placed directly on the tender area.

Settings and conduct

After meeting the inclusion and exclusion criteria, the patients are invited to participate in the project voluntarily to the physiotherapy centers of Semnan University of Medical Sciences. Patients with chronic non-specific low back pain caused by trigger point of gluteal muscles. The sharp and radicular pain are evaluated based on the anatomical position of the muscle and the pattern of pain. Patients are randomly divided into intervention and control groups through lottery

Participants/Inclusion and exclusion criteria

Inclusion VAS 3-7 Questionnaire Exclusion Cauda equina

Intervention groups

Control groups through the control group is divided into two groups of physiotherapy treatment for 5 weeks, including a Hot pack for 20 minutes and Ultrasound with a of Frequency 1 MHz for 5 minutes and TENS 5 Hz for 15 minutes with the shockwave off and the other group receive physiotherapy treatment with the shockwave.

Main outcome variables

The effect of adding shockwave on routine physiotherapy treatment on dynamic balance of patients with chronic nonspecific low back pain in both intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220127053838N1**

Registration date: **2022-02-11, 1400/11/22**

Registration timing: **prospective**

Last update: **2022-02-11, 1400/11/22**

Update count: **0**

Registration date

2022-02-11, 1400/11/22

Registrant information

Name

Seyed Ali asghar Ashtiyani

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

2022-04-08, 1401/01/19

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of radial extracorporeal shock wave therapy addition on routine physiotherapy treatment on the balance& pain & disability of patients with chronic non-specific low back pain caused by gluteal muscle trigger points

Public title

Radial extracorporeal shock wave therapy addition on routine physiotherapy treatment on the balance& pain & disability of patients with chronic non-specific low back pain caused by gluteal muscle trigger points

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age20-50 Have experienced back pain for at least more than 3 months The patient has an inability to function due to back pain The patient with low back pain has no history of lumbar surgery The patient's pain should be between 3 and 7 based on the visual pain questionnaire The patient has pain and trigger points in the gluteal area based on Travel and Simmons pain pattern Patient with gluteal muscle weakness on the dominant side compared to the healthy side based on manual muscle strength test (MMT)

Exclusion criteria:

Symptoms of Horsetail Syndrome include: Changes in urinary and fecal control, Saddle anesthesia, General anesthesia and general numbness Any symptoms of a serious spinal involvement include: chest pain, extensive paresthesia in the limbs, weakness in the lower limbs Any major cognitive impairment and severe aphasia Spinal fractures Postural vertigo Pregnancy

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the randomized permutation block method for random assignment. The procedure will be such that two and six blocks with a combination of A

(intervention group) and B (control group) will be the criteria for operation. Depending on the different combinations, each of the blocks is assigned a number as follows: Block 1: BBABAA Block 2: BA Block 3: BBAABA Block 4: BABBAA Block 5: AB Block 6: AB Block 7: BA Block 8: AB Block 9: BAAABB Using a table of random numbers, considering the numbers 1 to 9 and deleting the number zero, the blocks are selected respectively and the method of assigning patients to one of the groups A and B is done according to the selected blocks. After preparing a randomization list for each patient, they will have a number in the order of enrollment (from 1 to 34) A sealed envelope is provided with A or B written inside the envelope based on the compiled list. The researcher who does not know the main list, after registering the person entered to study and check the number of the person, opens the relevant envelope and realizes the type of intervention based on the contents of the envelope. In this way, the researcher realizes the type of intervention only after the patient enters the study and determines his eligibility, by opening the envelope, and finally we will have two balanced groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person doing the assessment is different from the person doing the intervention

Placebo

Used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Semnan University of Medical Sciences

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3514799442

Approval date

2022-01-29, 1400/11/09

Ethics committee reference number

IR.SEMUMS.REC.1400.296

Health conditions studied

1

Description of health condition studied

Chronic nonspecific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Static Balance

Timepoint

Sessions 1 and 10

Method of measurement

Biodex

2

Description

Dynamic Balance

Timepoint

Sessions 1 and 10

Method of measurement

Biodex

Secondary outcomes

1

Description

Pain

Timepoint

Sessions 1 and 10

Method of measurement

VAS

2

Description

Disability

Timepoint

Sessions 1 and 10

Method of measurement

Rolland-Morris

Intervention groups

1

Description

Intervention group: People in the intervention group, in addition to routine physiotherapy treatment, include 2 sessions per week for 5 weeks, a hot pack for 20 minutes, and ultrasound with a frequency of 1 MHz for 5 minutes, and TENS a frequency of 5 Hz for 15 minutes, and a shock wave for 2 sessions. Receives weekly for 5 weeks with intensity of 3, Frequency 10 and pulse 2000 for 7 minutes

Category

Rehabilitation

2

Description

Control group: Control group two days a week for 5 weeks of routine physiotherapy treatment which includes a hot pack for 20 minutes and ultrasound with a frequency of 1 MHz for 5 minutes and TENS with a frequency of 5 Hz for 15 minutes with shock wave off.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center ,Next to Nemat Ice Cream ,Quds Boulevard ,Semnan ,Iran

Full name of responsible person

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Sponsors / Funding sources

empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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