

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3722 6994

##### Email address

seyedashtiyani@gmail.com

##### 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

**Street address**

Semnan University of Medical Sciences and Health Services, Basij Street, Semnan, Iran

**City**

Semnan

**Province**

Semnan

**Postal code**

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

Seyed Ali Asghar Ashtiyani

##### Street address

Semnan University of Medical Sciences and Health Services, Basij Street, Semnan, Iran

##### City

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##### Province

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##### Postal code

3514799442

##### Phone

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##### Email

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## Sponsors / Funding sources

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Dr. Rozita Hedayati

#### Position

Associate Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiotherapy

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Seyed Ali Asghar Ashtiyani

**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
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**Postal code**  
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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