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 grouptwo 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
Cnclusion 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 intensityof 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
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3344 1022
Email
seyedashtiyani@gmail.com

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
Street address
Semnan University of Medical Sciences and Health Services, Basij Boulevard, Semnan, Iran
City
Semnan
Province
Semnan

Postal code
3514799442
Phone
+98 23 3344 1022
Email
rosehed@yahoo.com

Person responsible for scientific inquiries

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
Neuromuscular Rehabilitation Research Center, Next to Nemat Ice Cream, Quds Boulevard, Semnan, Iran
City
Semnan
Province
Semnan
Postal code
9837535196
Phone
+98 23 3332 8502
Email
seyedashtiyani@gmail.com

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
Neuromuscular Rehabilitation Research Center, Next to Nemat Ice Cream, Quds Boulevard, Semnan, Iran
City
Semnan
Province
Semnan
Postal code
9837535196
Phone
+98 23 3332 8502
Email
seyedashtiyani@gmail.com

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