Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Comparison Study of Low- energy versus Middle- energy Extracorporeal Shockwave Therapy on Pain Level and Functional Activity in Patients with Sub acute Pes Anserine Bursitis. a Single- Blind Randomized Clinical Trial

Protocol summary

Study aim
comparing effects of low versus middle extracorporeal shockwave therapy on pain level and functional activity of the patients with Sub- acute Pes Anserine Bursitis.v

Design
Single-Blinded RCT

Settings and conduct
Patients must be diagnosed with sub-acute pes anserine bursitis by a specialist rheumatologist. Blinding: patients will not have any idea that they are in the low-energy ESWT group or middle-energy ESWT group since the ESWT producer device is similar in both ESWT groups. Besides, the statistical analysis is accomplished by a researcher who will not have any idea about the type of intervention for each group. This project will be conducted in Physical Therapy department of Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Males and females 30- 55 yrs. 2. Educational level literate patients (at least Diploma) 3. Patients with subacute pes anserine bursitis (differential diagnosed by the rheumatologist specialist), 4. Knee pain ≥3 up to 7 on Numeric Pain Rating Scale (NPRS) at first session of assessment 5. The patients must be able to ambulate at least 30-meters on flat surface without a walking device and also able to perform simple physical exercises with minimal support. Exclusion Criteria: 1. Absent for two or more continuous sessions 2. Having an enormous increase on pain level 3. Having a severe decrease function in knee through the sessions 4. Having concomitant disease affecting their knee such as rheumatoid arthritis, recent injury, and surgery of knee 5. Having had intra- articular corticosteroid injection during last 6 months 6. History of cancer, dementia, neurologic deficits, heart pacemaker, pregnancy, uncontrolled cardiovascular disorders.

Intervention groups
Group1- Low–energy ESWT Group2- Middle–energy ESWT

Main outcome variables
Pain intensity, Functional Activity, Functional Mobility.

General information

Reason for update

Acronym
Pes Anserine Bursitis

IRCT registration information
IRCT registration number: **IRCT20221228056970N1**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-14, 1401/09/23

Expected recruitment end date
2023-04-01, 1402/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Study of Low- energy versus Middle- energy Extracorporeal Shockwave Therapy on Pain Level and Functional Activity in Patients with Sub acute Pes Anserine Bursitis. a Single- Blind Randomized Clinical Trial

Public title

Comparison Study of Low- energy versus Middle- energy Extracorporeal ShockwaveTreatment on Pain Level and Functional Activity in Patients with Sub acute Pes Anserine Bursitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30- 55 years. Both genders - males and females. Educational level literate patients (at least Diploma). Patients with subacute pes anserine bursitis (differential diagnosed by the rheumatologist specialist). Knee pain ≥3 up to 7 on Numeric Pain Rating Scale (NPRS) at first session of assessment. The patients must be able to ambulate at least 30 meters on flat surface without a walking device and also able to perform simple physical exercises with minimal support.

Exclusion criteria:

Absent for two or more continuous sessions. Have an enormous increase on pain level. Have a severe decrease function in knee through the sessions Have concomitant disease affecting their knee such as rheumatoid arthritis, recent injury, and surgery of knee. Have had intra- articular corticosteroid injection during last 6 months, history of cancer, dementia, neurologic deficits, heart pacemaker, pregnancy, uncontrolled cardiovascular disorders.

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization technique, so that each participant has the opportunity to choose the intervention group randomly by pick up a small piece of paper that help to identify type of interventions.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher considered blinding method so that the patients will not have any idea that they are in the conventional low- energy extracorporeal shockwave therapy group or middle- energy extracorporeal shockwave therapy group since the extracorporeal shockwave therapy producer device is similar in both ESWT groups. Besides, the statistical analysis is accomplished by a researcher wii not have any idea about the type of intervention for each group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery and Rehabilitation, Tehran University

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Buliding No. 1, The North Door of University, Poursina Street, Ghods St, Enghelab Avenue.

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Postal code

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Approval date

2022-12-11, 1401/09/20

Ethics committee reference number

IR.TUMS.FNM.REC.1401.125

Health conditions studied

1

Description of health condition studied

Sub-acute pes anserine bursitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

1. Numeric Pain Rating Scale (NRS) 2. McGill pain questionnaire (MPQ) 3. Western Ontario and McMaster Universities (WOMAC) 4. Timed Up and Go Test

Timepoint

Before intervention, after 2 weeks and after 3 weeks

Method of measurement

1. The Numeric Pain Rating Scale is a unidimensional measure of pain intensity, is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0 –10 integers) that best reflects the intensity of their pain. The common format is a horizontal bar or line. Similar to the pain VAS, the NRS is anchored by terms describing pain severity extremes. An 11- point numeric scale, 0 representing one pain extreme (no pain) and 10 representing the other pain extreme (pain as bad as you can imagine and worst pain imaginable). 2. Short-Form McGill Pain Questionnaire A multidimensional pain questionnaire. The main component of the SF-MPQ consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale as (0: none, 1 : mild, 2 : moderate or 3 : severe) . Three pain scores are derived from the sum of the intensity rank values of the words chosen for sensory, affective and total descriptors. The SF-MPQ also includes the Present Pain Intensity (PPI) index of the standard MPQ and a visual analogue scale (VAS). 3. Functional activity by Western Ontario and McMaster Universities (WOMAC) Osteoarthritis index. The WOMAC is a widely used, reliable, valid, and responsive measure of outcome in people with OA of the knee .It is a self-administered questionnaire consisting of 24 items divided into 3 subscales: Pain (5 items): during walking, using stairs, in bed, sitting or lying, and standing upright, Stiffness (2 items): after first walking and later in the day, Physical Function (17 items): using stairs, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet, heavy domestic duties, light domestic duties. The test questions are scored on a scale of 0-4, which correspond to: None (0), Mild (1), Moderate (2), Severe (3), and Extreme (4). The scores are totaled for each subscale (maximum totals, 20 [pain], 8 [stiffness], and 68 [physical function]) and normalized to a 100-point scale. A global score can be given by summing the three subscale scores .Higher scores on the WOMAC indicate worse pain, stiffness, and functional limitations. The area of assessment includes activities of daily living, functional mobility, gait, general health and quality of life. Participants will be given a standard paper form of WOMAC index questionnaire to fill it before and after the intervention. Arabic version of WOMAC will be used; because it will be easier for Arab patients to read and understand it without need for a translator, and to avoid translation bias. All patients who had difficulty in self- administration of WOMAC assessment questionnaires because they could not read and write were helped by their caregiver or by a person blinded to the purpose of the tools.

Secondary outcomes

1

Description

Timed Up and Go Test.

Timepoint

Before intervention, after 2 weeks and after 3 weeks.

Method of measurement

Functional Mobility by Timed Up and Go Test .TUG test is a performance-based measure of functional mobility that was initially developed to identify mobility and balance impairments in older adults. The test requires the subject to rise from a chair, walk 3.0 m at a comfortable pace to a mark placed on the floor, turn around at the 3.0 m mark, walk back to the starting point, and return to sitting in the chair. Individuals who take longer than 30 seconds to complete the test need physical assistance with transfers and generally cannot manage steps while Individuals who can complete the test in less than 20 seconds will likely be independently mobile and most can manage steps and walk outside the home.

Intervention groups

1

Description

Control group : Low energy extracorporeal shock wave therapy has been used previously and showed some improvements. Therefore, patients in this group will be considered as the control group. The patient in this group will receive low- energy extracorporeal shock wave therapy once per week for three weeks with characteristics of focus, 1,000 shocks/session, energy flux density EFD per shock 0.08 mJ/mm2. The device that will be used for this purpose is enPulsPro - Zimmer MedizinSysteme (Made in Germany). In addition, patients in this group will get standard care including quadriceps strengthening program consisting of isometric quadriceps exercise plus a short period (7 minutes) of mild heating (infra-red). The patients were instructed to sit down with a towel placed beneath their knees and press their knees against the towel while stretching their knees. Then, the patients were asked to maintain this position for 10 s and return to the starting position slowly for 70 contractions. The patients in this group will get 500 initial shocks as warm up with similar characteristics and then will be under the ESWT application. Each patient will be evaluated before and after 2 weeks and then 3 weeks of physical therapy interventions.

Category

Rehabilitation

2

Description

Intervention group: The patient in this group will receive middle- energy extracorporeal shock wave therapy once per week for three weeks with characteristics of focus, 2,000 shocks/session, energy flux density EFD per shock 0.16 mJ/mm2. The device that will be used for this purpose is enPulsPro - Zimmer MedizinSysteme (Made in Germany). In addition, patients in this group will get standard care including quadriceps strengthening program consisting of isometric quadriceps exercise plus a short period (7 minutes) of mild heating (infra-red). The patients were instructed to sit down with a towel placed beneath their knees and press their knees against the towel while stretching their knees. Then, the patients

were asked to maintain this position for 10 s and return to the starting position slowly for 70 contractions. The patients in this group will get 500 initial shocks as warm up with similar characteristics and then will be under the ESWT application. Each patient will be evaluated before and after 2 weeks and then 3 weeks of physical therapy interventions.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Physiotherapy of Tehran University of Medical Sciences.

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Raghad Talib Taha Khazraji

Position
Pt. MSc Candidate

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because sharing IPD is useless according to the our study, We should consider all the sample size.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the primary outcome measure will be shared.
When the data will become available and for how long
These data will become available 2 months after publication.
To whom data/document is available
The results will be available for physiotherapists and people working in academic instutions.
Under which criteria data/document could be used
people can use the data only for the rehabilitative purposes.
From where data/document is obtainable
Mrs Raghad Talib Taha Khazraji will be in charge of communication via E-mail: raghad_talib2008@yahoo.com
What processes are involved for a request to access data/document
After receiving the request and the main purposes for needing the data, we will response to the request maximally to one month.
Comments