

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparing the efficacy of local corticosteroid injection and Extracorporeal shockwave therapy in patients diagnosed with pes anserine bursitis

Protocol summary

Study aim

The aim of this study will be compare the effectiveness of topical corticosteroid injection and extracorporeal shockwave therapy on pes anserine thickness, pain intensity and quality of life in patients with pes anserine bursitis.

Design

This study is a phase 3 clinical trial that will be performed on 60 patients with pes anserine bursitis.. Allocation of patients will be done randomly with computer software in two treatment group : topical corticosteroid injection and ESWT.

Settings and conduct

In this study, which will be performed at Besat Hospital in Hamadan, the effect of two treatments of local injection of corticosteroids and ESWT in patients with pes anserine bursitis.will be evaluated and compared. The outcome evaluator will not be aware of the type of intervention (single blinded)

Participants/Inclusion and exclusion criteria

Participants will be patients 18 to 65 years old with pes anserine bursitis . At least three months of history of disease, and minimum pain intensity above 3 based on visual analog scale are inclusion criteria and comorbidity of other knee, neurological and motor diseases, systemic diseases, history of surgery or recent trauma of Knee, vascular disease, and corticosteroid therapy history in pas 4 months are not been included in the study

Intervention groups

The intervention groups consisted of two groups of 30 people receiving local corticosteroid injections and ESWT, which will be randomly selected. The ESWT group will undergo an ESWT once a session per week for three weeks and the second group will receive a local corticosteroid injection containing 40 mg of methylprednisolone and 1 ml of 1% lidocaine under ultrasound guidance.

Main outcome variables

Outcomes of the intervention include changes in pes anserine thickness, pain, and quality of life that will be assessed before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N16**

Registration date: **2021-07-17, 1400/04/26**

Registration timing: **prospective**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

Registration date

2021-07-17, 1400/04/26

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Of Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of local corticosteroid injection and Extracorporeal shockwave therapy in patients diagnosed with pes anserine bursitis

Public title

Comparison of the effect of corticosteroids and extracorporeal shockwave therapy in the treatment of pes anserine bursitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of PAB according to clinical and paraclinical criteria by a specialist physician
 Diagnosis period at least 3 months
 Age 65-18 years
 Pain severity greater than 3 according to VAS scale

Exclusion criteria:

Comorbidity of other knee diseases such as advanced osteoarthritis, infection and ...
 History of recent knee surgery or trauma
 Vascular disease
 History of corticosteroid therapy during the last 4 months

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

60 eligible patients will be selected by convenience sampling. The samples will be randomly coded in two groups E and C with computer software and the relevant codes will be entered in the raw checklists. Upon patient referral, one of the checklists will be randomly assigned to each patient. If the selected code is E, the patient will be allocated to ESWT treatment group and if C will be allocated to topical corticosteroid injection group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single blinded study, the evaluator of intervention outcomes will be blinded about the patients' group therapy.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan University of Medical Science

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Shahid Fahmideh Ave

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6517838697

Approval date

2021-04-10, 1400/01/21

Ethics committee reference number

IR.UMSHA.REC.1400.069

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

Pes anserine bursitis

ICD-10 code

M70.5

ICD-10 code description

Other bursitis of knee

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

Pes Anserin thickness changes

Timepoint

Before, 1 and 3 month after treatment

Method of measurement

Sonography

2**Description**

Pain severity

Timepoint

Before, 1 and 3 month after treatment

Method of measurement

Visual Analogues Scale

Secondary outcomes**1****Description**

Patients quality of life

Timepoint

Before, 1 and 3 months after treatment

Method of measurement

Sf-12 questionnaire

2**Description**

Treatment complications

Timepoint

1 and 3 months after treatment

Method of measurement

Examination and interview

Intervention groups**1****Description**

Intervention group: Patients in this group will receive extra corporeal shock wave therapy (ESWT). ESWT will be done in one session per week for 3 consecutive weeks. ESWT will be performed while the patient is lying on a quiet bed at the point where the greatest intensity of tenderness is found. Device settings: frequency 4 Hz, pulse 1500, energy 20.15 mj / mm

Category

Treatment - Other

2**Description**

Intervention group: Patients in this group will receive a local injection of corticosteroids. For this purpose, first knee ultrasound is performed and the appropriate point for injection will be identified and marked; Then, under ultrasound guidance, 40 mg of methylprednisolone and 1 ml of 1% lidocaine will be injected at the marked site.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Lobat Majidi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

MSc in epidemiology/ Community Medicine MS

Latest degree

Master

Other areas of specialty/work

Epidemiology

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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