Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of topical corticosteroid injection and high-level laser therapy in patients with acute post-Anserin bursitis(PAB)

Protocol summary

Study aim

Comparison of the effect of topical cortico-steroid and high-level laser therapy on pes anserine bursitis thickness, pain intensity of knee and quality of life in patients with acute PAB

Design

A clinical trial with a control group, with parallel groups, single blind, randomized phase 3 will be performed on 60 patients. The envelope method will be used for randomization.

Settings and conduct

This study will be performed to compare two rehabilitation methods in patients with acute pes anserine bursitis in the physical medicine clinic of Besat Hospital in Hamadan. The evaluator will be blinded to the patients' group therapy. Group A will use a gallium arsenide diode laser (model 4 cube-laser-K) with a wavelength of 1064 nm, an output power of 8 watts, and an average energy intensity of 4 joules per square centimeter. Group B will receive a topical injection of corticosteroids under a sono guide of 1 ml of triamcinolone and 1 ml of 2% lidocaine as a single dose.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of PAB according to clinical criteria and imaging finding, and age 18-65 years, Non-entry criteria: Comorbidity with rheumatoid arthritis, and treated with corticosteroids at study time or during the last 4 months

Intervention groups

Group A will be use of gallium aluminum arsenide diode laser (model 4 cube-laser-K) with a wavelength of 1064 nm, an output power of 8 watts, and an average energy intensity of 4 joules per square centimeter. The total duration of treatment in each session will be 5-7 minutes for 3 consecutive weeks (5 sessions). Group B will receive topical corticosteroid injections under sono guide 1 ml triamcinolone with 1 ml lidocaine 2% single dose.

Main outcome variables

Pes Anserin changes including thickness, tendonitis and bursitis, severity of knee pain, quality of life associated with knee pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N19**
Registration date: **2021-12-28, 1400/10/07**
Registration timing: **prospective**

Last update: **2021-12-28, 1400/10/07**
Update count: **0**

Registration date

2021-12-28, 1400/10/07

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Of Science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of topical corticosteroid injection and high-level laser therapy in patients with acute post-Anserin bursitis(PAB)

Public title

Treatment of acute post-Anserin bursitis with topical injection of corticosteroids and high-level laser therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of PAB according to clinical criteria and imaging by a specialist physician At least 3 months after diagnosis Age 18-65 years Minimum pain intensity according to VAS> 3

Exclusion criteria:

Comorbidity with other diseases such as: advanced osteoarthritis, infection, neurological and motor diseases (stroke, Parkinson's, myopathies, neuropathies, ...), other systemic diseases such as rheumatoid arthritis and heart disease History of recent knee surgery or trauma Treatment with corticosteroid now or during the last 4 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

We made 60 cards and write letter I on 30 for Intervention and on the other 30 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter I or C patients will be assigned to intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who asses outcome will be blinded to the patients' group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan Univercity of Medical Science

Street address

shahid fahmideh

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Province

Hamadan

Postal code

6517838697

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.UMSHA.REC.1400.224

Health conditions studied

1

Description of health condition studied

pes anserine bursitis knee

ICD-10 code

M06.26

ICD-10 code description

Rheumatoid bursitis, knee

Primary outcomes

1

Description

Pes anserine bursitis thickness changes

Timepoint

Before treatment, one month later, and three months after treatment

Method of measurement

sonography

2

Description

pain severity of knee

Timepoint

Before treatment, one month later, and three months after treatment

Method of measurement

By Visual Analogue Scale

Secondary outcomes

1

Description
Patients Quality of life
Timepoint
Before treatment, one month and three months after starting treatment
Method of measurement
With SF-12 Quality of Life Questionnaire

Intervention groups

1

Description
Intervention group: One group will undergo high-level laser therapy. For this purpose, gallium aluminum arsenide diode laser (model 4 cube-laser-K) with a wavelength of 1064 nm, an output power of 8 watts, and an average energy intensity of 4 joules per square centimeter will be used . The total duration of treatment in each session will be 5-7 minutes for 3 consecutive weeks (5 sessions).
Category
Rehabilitation

2

Description
Intervention group: The other group will receive a topical injection of corticosteroids. The corticosteroid contains 1 ml of triamcinolone and 1 ml of 2% lidocaine, which will be injected topically into the knee area under the sono guide single dose.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr Behnaz Alaei
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Sponsors / Funding sources

1

Sponsor
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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
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
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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