Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of comparison between acupuncture and high intensity laser on improving pain and upper limb function in lateral epicondylitis

Protocol summary

Study aim

This study aims to compare the effects of high-power laser and acupuncture on pain and upper-limb function in patients with lateral epicondylitis

Design

A two-arm clinical trial with parallel groups, unblinded and randomized, conducted on 34 patients. Balanced block randomization was used for allocation.

Settings and conduct

Patients with lateral epicondylitis who presented to the clinic of Imam Reza Hospital in Birjand will be included in the study if they are eligible and will be divided into two intervention groups of acupuncture and high-intensity laser therapy according to the balanced block randomization method

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of lateral epicondylitis with at least 3 months of pain and tenderness unresponsive to conservative treatments. Exclusion Criteria: Diagnosis of rheumatologic diseases, rheumatoid arthritis, Systemic Lupus Erythematosus،, active malignancy, pregnancy, severe psychiatric disorders, and recent interventions in the elbow area including surgery or corticosteroid injection within the past 6 months, opioid compounds users.

Intervention groups

Intervention Group 1: Laser therapy using the NET-LASER device with an energy output of 1800 Joules, applied for 5 minutes during each session. Participants will undergo 5 treatment sessions, with 3 sessions per week, using a laser with a wavelength of 940 nm and power of 10 Watts. Intervention Group 2: Acupuncture therapy performed by a licensed physical medicine specialist using a Western approach. The acupuncture will target the extensor muscles of the elbow, with sterile needles of size 0.25 mm and length 25 mm from the Needle Acupuncture SMC brand. Participants will receive 5 treatment sessions, with 3 sessions per week.

Main outcome variables

Pain score based on the Visual Analogue Scale, Upper limb function score based on Quickdash questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260404069021N1**
Registration date: **2026-05-07, 1405/02/17**
Registration timing: **retrospective**

Last update: **2026-05-07, 1405/02/17**
Update count: **0**

Registration date

2026-05-07, 1405/02/17

Registrant information

Name

amirhossein ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3607 3317

Email address

amirhossein.a@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-17, 1404/07/25

Expected recruitment end date

2026-01-15, 1404/10/25

Actual recruitment start date

2025-10-17, 1404/07/25

Actual recruitment end date

2026-02-14, 1404/11/25

Trial completion date
2026-05-05, 1405/02/15

Scientific title
Clinical trial of comparison between acupuncture and high intensity laser on improving pain and upper limb function in lateral epicondylitis

Public title
Comparison of acupuncture and high intensity laser in lateral epicondylitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Persistent pain and tenderness over the lateral epicondyle for at least three months, unresponsive to conservative management Exacerbation of pain over the lateral epicondyle during resisted wrist extension

Exclusion criteria:
Diagnosis of rheumatoid arthritis Presence of a major psychiatric disorder lack of consent to participate Presence of active malignancy. Pregnancy. Presence of rheumatologic diseases or current use of rheumatologic medications. History of corticosteroid injection within the past 6 months. Prior elbow surgery. Diagnosis of systemic lupus erythematosus (SLE). opioid compounds users

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **34**
Actual sample size reached: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Patient allocation into two groups, intervention (high-power laser) and control (acupuncture), was performed using the Balanced Block Randomization method. For generating the random sequence, fixed block sizes of 4 with an allocation ratio of 1:1 were used (in each block, 2 individuals were assigned to the laser group and 2 to the acupuncture group). The random sequence was generated by an individual not involved in the treatment and patient assessment process, utilizing the R software and the 'blockrand' package. For Allocation Concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) were employed. Each envelope was labeled with the patient's number, and the type of intervention was placed inside, with the respective envelope being opened only after the patient entered the study and provided informed consent

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences, Ghaffari St., Birjand, South Khorasan, Iran

City
Birjand

Province
South Khorasan

Postal code
9717853076

Approval date
2025-10-08, 1404/07/16

Ethics committee reference number
IR.BUMS.REC.1404.309

Health conditions studied

1

Description of health condition studied
Lateral epicondylitis

ICD-10 code
M77.1

ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
The pain score based on the Visual analogue scale

Timepoint
Baseline (before intervention), post-intervention (after 2 weeks of treatment), and follow-up (1 month after the end of the intervention/week 6)

Method of measurement
Visual analogue scale

2

Description
Upper limb function score based on Quickdash questionnaire

Timepoint
Baseline (before intervention), post-intervention (after 2

weeks of treatment), and follow-up (1 month after the end of the intervention/week 6)

Method of measurement

Quickdash questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Medical acupuncture based on Western approach will be performed by a specialist in physical medicine. This group will consist of 5 treatment sessions, with patients receiving therapy three times a week. The treatment will be applied to the origin of extensor muscles of the elbow. Additional details regarding the intervention: Number of sessions: 5 sessions. Duration of each session: 45 minutes. Frequency per week: three times per week. Method of administration: Needles are inserted directly into specific points according to the treatment protocol. Equipment and consumables: Acupuncture needles from the brand SMC, with specifications of 0.25 mm diameter and 25 mm length, produced according to safety and hygiene standards.

Category

Treatment - Devices

2

Description

Intervention Group 2: High-intensity laser therapy will be administered by a specialist in physical medicine. This group will consist of 5 treatment sessions, with patients receiving therapy three times a week. Additional details regarding the intervention: Therapeutic Modality: High-intensity laser therapy using the LASER-NET device. Wavelength: 940 nm. Power: 10 Watts. Energy Delivered: 1800 Joules Duration of each session: 5 minutes. Frequency per week: three times per week. Method of administration: The laser will be applied according to the treatment protocol. Equipment and consumables: LASER-NET high-intensity laser device.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic, Imam Reza Hospital

Full name of responsible person

Amirhossein Ahmadi

Street address

Imam Reza Clinic, Imam Reza Hospital, Ayatollah Taleghani Street, Birjand

City

Birjand

Province

South Khorasan

Postal code

9717853076

Phone

+98 915 112 5179

Email

amirhossein.a@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr.Masoud Yousefi

Street address

Central Organization of Birjand University of Medical Sciences, Ghaffari Street, Birjand, South Khorasan Province, Iran

City

Birjand

Province

South Khorasan

Postal code

9717853076

Phone

+98 56 3238 1200

Email

Masoud.yousefi@bums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Amirhossein Ahmadi

Position

Medical student

Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No. 85, Alley 40, Emamat Street, Azadshahr Boulevard, Mashhad, Razavi Khorasan Province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9188779677
Phone
+98 51 3607 3317
Email
amirhossein.a@bums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Amirhossein Ahmadi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No. 85, Alley 40, Emamat Street, Azadshahr Boulevard, Mashhad, Razavi Khorasan Province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
988779677
Phone
+98 51 3607 3317
Email
amirhossein.a@bums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Amirhossein Ahmadi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
No. 85, Alley 40, Emamat Street, Azadshahr Boulevard, Mashhad, Razavi Khorasan Province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9188779677
Phone
+98 51 3607 3317
Email
amirhossein.a@bums.ac.ir

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
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available