

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of high-level laser and quadriceps muscle strengthening exercises using biofeedback on pain and function in patients with knee osteoarthritis

Protocol summary

2023-03-17, 1401/12/26

Study aim

Investigating the effect of high-power laser and quadriceps muscle strengthening exercises using biofeedback on pain and function of patients with knee osteoarthritis

Design

People were randomly divided into two treatment groups A and B in a blocked way through block randomization.

Settings and conduct

Birjand, Iran

Participants/Inclusion and exclusion criteria

The study sample in this study includes knee osteoarthritis patients referred to the clinic of Imam Reza hospital in Birjand, who was referred by a specialist after the diagnosis of knee osteoarthritis.

Intervention groups

Group A was treated with high-power laser and exercise therapy for 10 sessions and group B was treated with quadriceps muscle strengthening exercises using biofeedback and exercise therapy for 10 sessions.

Main outcome variables

-Evaluation of knee pain severity scores of patients based on VAS criteria -Completion of the WOMAC questionnaire for all participants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221115056509N1**

Registration date: **2023-03-17, 1401/12/26**

Registration timing: **retrospective**

Last update: **2023-03-17, 1401/12/26**

Update count: **0**

Registration date

Registrant information

Name

Fatemeh Jazebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3242 2111

Email address

jazebi1998@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-01-24, 1401/11/04

Actual recruitment start date

2022-04-21, 1401/02/01

Actual recruitment end date

2023-01-24, 1401/11/04

Trial completion date

2023-01-25, 1401/11/05

Scientific title

Comparison of the effect of high-level laser and quadriceps muscle strengthening exercises using biofeedback on pain and function in patients with knee osteoarthritis

Public title

The effect of high power laser and quadriceps strengthening exercises on osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being on stage two or three of knee osteoarthritis A history of continuous knee pain caused by osteoarthritis for at least 6 months Minimum pain intensity of 3 based on Visual Analog Scale (VAS) criteria before the intervention Body mass index less than or equal to 30 kg/m² No using non-steroidal anti-inflammatory drugs and steroids before or during the intervention A healthy mental state and full satisfaction to participate in the research

Exclusion criteria:

Patients under 18 years old pregnant women Non-completion of evaluation and treatment programs Irregular attendance in the treatment program The use of intra-articular injections during the last year before the study and during the study A history of knee injury and surgery Suffering from neuromuscular diseases and malignant tumors Having bone implants in the lower limbs Suffering from any rheumatological disease that requires steroid drugs Participation in exercise therapy and physiotherapy programs during the last 6 months

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After meeting the inclusion criteria, people were randomly divided into two treatment groups (A and B) through block randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

People were randomly divided into two treatment groups (A and B) through block randomization, and they were unaware of the way of intervention in the other group.

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

Ghaffari St., Birjand University of Medical Sciences, Birjand, Iran

City

Birjand

Province

South Khorasan

Postal code

9717853076

Approval date

2022-05-16, 1401/02/26

Ethics committee reference number

IR.BUMS.REC.1401.083

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

Osteoarthritis

ICD-10 code

M15-M19

ICD-10 code description

Diseases of the musculoskeletal system and connective tissue(M00-M99)

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

Evaluation of pain using a visual analogue scale (VAS)

Timepoint

After 10 sessions of laser therapy and after biofeedback and exercise therapy

Method of measurement

VAS criteria

Secondary outcomes

empty

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

Intervention group: Group A was treated with high-power laser and exercise therapy for 10 sessions

Category

Rehabilitation

2**Description**

Intervention group: or group B that was treated with quadriceps muscle strengthening exercises using biofeedback and exercise therapy for 10 sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Medicine and Rehabilitation Clinic of Imam Reza Hospital, Birjand

Full name of responsible person

Fatemeh Jazebi

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Ghaffari St, Birjand, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

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

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

Maryam Rahimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fateme Jazebi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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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

There is no information to publish

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

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

Title and more details about the data/document

Only a part of the data, such as the information related to the main result can be shared.

When the data will become available and for how long

The access period starts 6 months after publishing the result

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For professors and students

From where data/document is obtainable

Send a request email to Jazebi1998@gmail.com

What processes are involved for a request to access data/document

Send a request email to Jazebi1998@gmail.com

Comments