

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effects of low level laser therapy on pain, range of motion and edema in people suffering from patellofemoral pain syndrome

Protocol summary

Study aim

To determine and compare the mean pain, range of motion and edema in patients with patellofemoral pain syndrome before treatment , after 10 sessions treatment in low level laser therapy and control groups.

Design

Randomized controlled clinical trial with parallel groups and double blinded

Settings and conduct

The rationale for this research is to determine the effects of low level laser therapy on pain, range of motion and edema in patients with patellofemoral pain syndrome. This study will be conducted at poursina hospital and neither patients no examiner know the grouping and treatments procedures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 to 45years. Patellofemoral pain syndrome diagnosis: According to orthopedic physician assessment; Exclusion criteria: Patients with patellofemoral pain syndrome without effusion . Patients with arthrosis grade III and IV according to X-Ray. Patients with tibia, patella, femur and fibula fractures. Patients with history of femur and other bones surgery, or meniscus and cruciate ligaments and tendon surgery. Patients with complete soft tissues tear such as meniscus and cruciate ligaments. Patients with referral pain form lumbar or hip and local infections. Addict or pregnant individuals. Patients that took part in physiotherapy program about during 2 weeks ago. Patients with history of rheumatoid diseases such as rheumatoid arthritis.

Intervention groups

Control group receive routine physical therapy treatments and intervention group receive routine physical therapy as well as low level laser therapy

Main outcome variables

Knee pain; Knee range of motion; Knee effusion;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N6**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **prospective**

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

Registration date

2019-05-28, 1398/03/07

Registrant information

Name

Kamran Ezzati

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of low level laser therapy on pain, range of motion and edema in people suffering from patellofemoral pain syndrome

Public title

The effects of laser therapy on pain and edema

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patellofemoral pain syndrome diagnosis: According to orthopedic physician assessment -Age between 20-45 years

Exclusion criteria:

Patients with patellofemoral pain syndrome without effusion. Patients with arthrosis grade III and IV; fractures; history of surgery; patients with complete soft tissues tear.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

The grouping method will be Permuted block randomization . So, blocks of 10 people including 5 participants in the intervention group and 5 participants in the control group are allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The examiner won't know anything about the kind of treatment. The Patients and therapists will also not know anything about grouping and kind of interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

5th floor, Central office of Guilan University of Medical Sciences, Namjoo St., Rasht, Iran

City

Rasht

Province

Guilan

Postal code

۴۱۹۳۷۱۳۱۹۴

Approval date

2019-05-16, 1398/02/26

Ethics committee reference number

IR.GUMS.REC.1398.066

Health conditions studied

1

Description of health condition studied

Patellofemoral pain syndrome

ICD-10 code

M22.2X

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description

Pain

Timepoint

Before and after intervention

Method of measurement

Visual Analogue Scale

2

Description

Edema score

Timepoint

Before and after intervention

Method of measurement

Tape

3

Description

Range of motion

Timepoint

Before and after intervention

Method of measurement

Goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the knee of the individual. The patient will feel mild heat. 2- Treatment with transcutaneous electrical nerve stimulation(TENS) type brief for 20 minutes. In this method, four electrodes on the sides of the knee will be used. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations. 3- Exercise for strengthening muscle should include five exercises from the third to the tenth sessions twice daily.

Category

Rehabilitation

2

Description

Intervention group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the knee of the individual. The patient will feel mild heat. 2- Treatment with TENS type brief for 20 minutes. In this method, four electrodes on the sides of the knee will be used. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations. 3- Exercise for strengthening muscle should include five exercises from the third to the tenth sessions twice daily. 4. Laser therapy: In this study, a laser with a wavelength of 905 nm, an energy density of 8 J / cm², a power of 50 mW in 10 points of the knee including 4 points on the anterior knee , 2 points on the medial knee, 2 points on the lateral knee, 2 points on the posterior knee. The radiation time will be 91s for each point.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina hospital

Full name of responsible person

Kamran Ezzati

Street address

Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

Deputy of Research, Opposie to Azodi Stadium, Namjoo St, Rasht, Iran

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9131293466

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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

Guilan 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

Guilan University of Medical Sciences, Deputy of Research

Full name of responsible person

Sosan Komaei

Position

Bachelor of science

Latest degree

Bachelor

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Assistant professor

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Sharing is done after the end of the study. The total potential data can be shared after unidentifications of individuals.

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Researchers working in universities

Under which criteria data/document could be used

Researchers working in universities

From where data/document is obtainable

Address: Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht. Ez_kamran@yahoo.com

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

A written request for data from the relevant university with the name and academic degree of the researcher

Comments