Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 / cm 2, 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person
Shadman Nemati

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

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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

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Person responsible for updating data

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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 publicating 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
Adress: 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