

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Effect of low level laser and placebo laser on pain and function in subjects with patellofemoral pain syndrome: A Pilot Randomized Clinical Trial

Protocol summary

Study aim

To compare the effects of three groups including standard physical therapy alone, low level LASER plus standard physical therapy and placebo LASER plus standard physical therapy with each other on pain and function in subjects with patellofemoral pain syndrome.

Design

A pilot randomized clinical trial with placebo and control groups, community based, Triple-blind (participant, examiner and analyzer) with a parallel design

Settings and conduct

Hatef Physical Therapy Center. participant, examiner and analyzer are blind in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects from both genders with patellofemoral pain Exclusion criteria: other problems and diseases associated with knee pain

Intervention groups

Standard physical therapy: education (using a pamphlet), using OFF ultrasound, stretching exercises for hamstring, plantar flexors, quadriceps and iliotibial band muscles and strengthening exercises for quadriceps and hip muscles. Standard physical therapy plus low level LASER: Standard physical therapy plus 808 nm, 200 mW, 4 J Ga-Al-As LASER over 5 points around the patella for 20 seconds per point Standard physical therapy plus placebo LASER: Standard physical therapy plus OFF LASER over 5 points around the patella for 20 seconds per point The treatment plan will be for each group of ten sessions, three sessions per week.

Main outcome variables

Pain; Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150131020888N9**

Registration date: **2018-08-04, 1397/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-04, 1397/05/13**

Update count: **0**

Registration date

2018-08-04, 1397/05/13

Registrant information

Name

Zahra Sadat Rezaeian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5042

Email address

zrezaeian@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-28, 1397/04/07

Expected recruitment end date

2019-02-26, 1397/12/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of low level laser and placebo

laser on pain and function in subjects with patellofemoral pain syndrome: A Pilot Randomized Clinical Trial	
Public title	The Effect of low level LASER on pain and function in subjects with anterior knee pain
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Presence anterior or retro patellar pain only in one limb The report of pain during a day at least in 2 functional activities including prolonged sitting, climbing stairs, squatting, running, double kneeling, jumping Score of at least 3 on the visual analog scale (VAS) The pain will be reported in the squat on one leg for 10 seconds Subjects have anterior knee pain at least in the past three months Age from 18 to 40 years Exclusion criteria: Traumatic injuries of the low back and lower extremities Any signs or symptoms or MRI findings based on intra-articular pathologic conditions such as effusion, meniscal, or cruciate or collateral ligament involvement Subluxation and dislocation of the patella Other musculoskeletal injuries in lower extremities hip or lumbar referred pain Any symptoms or evidence of knee osteoarthritis in X-rays Infectious disease, rheumatoid arthritis, autoimmune disease, cancer and systemic diseases Corticosteroid injections and received physical therapy in the last 3 months, and received opioid and analgesic drugs in the last 72 hours Epilepsy, heart problems and heart pacemaker Active athlete BMI>30kg/m² Surgery of the lower limbs and lower back History the use of LASERs due to prejudices about the effect of the intervention
Age	From 18 years old to 40 years old
Gender	Both
Phase	N/A
Groups that have been masked	- Participant - Investigator - Data analyser
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	The volunteers will be assigned to three groups randomly using the random numbered table codes. an unaware person in the research method will select the codes from the random numbers table.
Blinding (investigator's opinion)	Triple blinded
Blinding description	This study is a Triple-blind randomized clinical trial (participant, examiner and analyzer) with a parallel design. LASER is performed by a physical therapist in two groups of laser and placebo. This person has no role in evaluating participants, other sections of treatment and recording information. Participants can not recognize, whether LASER devices is on or off. The same physical therapist who is blind to study groups will supervise standard physical therapy in all groups. to ensure participant blinding to study groups they all will receive therapeutic ultrasound in OFF state. A comprehensive clinical assessment will be performed by a physical therapist who is unaware of the research groups (student). Data analysis will be done by an unknown person in the research method.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics Committee of Isfahan University of Medical Sciences Street address Secretariat of the Ethics Committee, Room 209, Second Floor, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan, Iran City Isfahan Province Isfahan Postal code 81745-164 Approval date 2018-07-04, 1397/04/13 Ethics committee reference number http://ethics.research.ac.ir/IR.MUI.RESEARCH.REC.1397.035
Health conditions studied	1 Description of health condition studied patellofemoral pain syndrome ICD-10 code M22.4 ICD-10 code description Chondromalacia patellae
Primary outcomes	1 Description pain

Timepoint

the first session just before the intervention and at the tenth session after the end of the treatment plan

Method of measurement

Visual Analogue Scale (VAS)-Persian version of Kujala questionnaire

2**Description**

function

Timepoint

the first session just before the intervention and at the tenth session after the end of the treatment plan

Method of measurement

Persian version of Kujala questionnaire- step down test

Secondary outcomes

empty

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

Intervention group: standard physical therapy plus low-level LASER group: Participants in this group receive active LASER plus standard physical therapy. LASERs will be used at the beginning of the session before any other intervention. Subjects will receive LASER in supine position. The probe will be in direct and full contact with the tissue at 90 ° angle. The LASER group will be treated with low level Gallium-Aluminum-Arsenide (Ga-Al-As) LASER, with a wavelength of 808 nm, output power of 200 mW, continuous mode, Beam spot size of 1 cm², dose of 4 J/cm² (each point), and energy of 4J for 20 seconds on each point. LASER will be radiated over five points around the patella. The total energy and total radiation time for each session will be 20 Jules and 100 seconds (one minute and 40 seconds) respectively. Participants will receive standard physical therapy after completing laser therapy. At first OFF ultrasound will be used over the patella. According to Manchester consensus statement, therapeutic exercises is the treatment of choice for patellofemoral pain syndrome. Each training session will begin with 5 minutes' warm up, continue with stretching and strengthening exercises, and finally, cool down for 5 minutes. Stretching exercises for hamstring, plantar flexors, quadriceps and iliotibial band: 3 repetitions of 30s for each muscle. - Strengthening exercises: semi squat (0-45 degrees), Seated knee extension (90-45 degrees), SLR , hip abduction with weights (side lying), hip abduction against elastic band (standing), hip lateral rotation against elastic band (sitting). Each exercise will be performed in three sets of 10 repetitions. Interval for rest and recovery between sets will be 3 minutes. External resistance during training will be standardized as 70% of the 1-repetition maximum (1RM). The elastic band resistant will be individualized as maximum resistant which each subject can perform in 10 repetitions (10 RM for Thera Band).

Category

Rehabilitation

2**Description**

Intervention group: standard physical therapy plus placebo LASER group: The participants in this group receive LASER off plus standard physical therapy. In this group, the LASER device will turn off all the time. Participants will receive standard physical therapy after completing the LASER off Program. At first OFF ultrasound will be used over the patella. According to Manchester consensus statement, therapeutic exercises is the treatment of choice for patellofemoral pain syndrome. Each training session will begin with 5 minutes' warm up, continue with stretching and strengthening exercises, and finally, cool down for 5 minutes. Stretching exercises for hamstring, plantar flexors, quadriceps and iliotibial band: 3 repetitions of 30s for each muscle. Strengthening exercises: semi squat (0-45 degrees), Seated knee extension (90-45 degrees), SLR , hip abduction with weights (side lying), hip abduction against elastic band (standing), hip lateral rotation against elastic band (sitting). Each exercise will be performed in three sets of 10 repetitions. Interval for rest and recovery between sets will be 3 minutes. External resistance during training will be standardized as 70% of the 1-repetition maximum (1RM). The elastic band resistant will be individualized as maximum resistant which each subject can perform in 10 repetitions (10 RM for Thera Band).

Category

Rehabilitation

3**Description**

Control group: standard physical therapy alone: Participants in this group will receive only standard physical therapy. At first OFF ultrasound will be used over the patella. According to Manchester consensus statement, therapeutic exercises are the treatment of choice for patellofemoral pain syndrome. Each training session will begin with 5 minutes' warm up, continue with stretching and strengthening exercises, and finally, cool down for 5 minutes. Stretching exercises for hamstring, plantar flexors, quadriceps and iliotibial band: 3 repetitions of 30s for each muscle. Strengthening exercises: semi squat (0-45 degrees), Seated knee extension (90-45 degrees), SLR , hip abduction with weights (side lying), hip abduction against elastic band (standing), hip lateral rotation against elastic band (sitting). Each exercise will be performed in three sets of 10 repetitions. Interval for rest and recovery between sets will be 3 minutes. External resistance during training will be standardized as 70% of the 1-repetition maximum (1RM). The elastic band resistant will be individualized as maximum resistant which each subject can perform in 10 repetitions (10 RM for Thera Band).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hatef Physical Therapy Center

Full name of responsible person

Dr. Zahra Sadat Rezaeian

Street address

No. 16, 2nd Floor, Salam Building., before Ostad
Shahriar T intersection, Robat street., Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8154739711

Phone

+98 31 3442 1625

Fax

+98 31 3668 7270

Email

zrezaeian@yahoo.com

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA-AAJ&hl=en>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Vice
Chancellery of Research and Technology

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellery of Research and Technology, Isfahan
University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81745-164

Phone

+98 31 3792 5012

Fax

+98 31 3668 7270

Email

zrezaeian@rehab.mui.ac.ir

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA-AAJ&hl=en>

Grant name**Grant code / Reference number**

297030

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Vice Chancellery
of Research and Technology

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**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Zahra Sadat Rezaeian

Position

PhD, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Hezar Jarib Ave. Isfahan University of Medical
Sciences, Faculty of Rehabilitation Sciences

City

Isfahan

Province

Isfahan

Postal code

81745-164

Phone

00983137925012; 00983137925042

Fax

+98 31 3668 7270

Email

zrezaeian@yahoo.com

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA-AAJ&hl=en>

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Zahra Sadat Rezaeian

Position

PhD, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Hezar Jarib Ave. Isfahan University of Medical Sciences, Faculty of Rehabilitation Sciences

City

Isfahan

Province

Isfahan

Postal code

81745-164

Phone

00983137925012; 00983137925042

Fax

+98 31 3668 7270

Email

zrezaeian@yahoo.com

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA&hl=en>

City

Isfahan

Province

Isfahan

Postal code

81745-164

Phone

00983137925012; 00983137925042

Fax

+98 31 3668 7270

Email

zrezaeian@yahoo.com

Web page address

<http://scholar.google.com/citations?user=FXzUASAAA&hl=en>

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Zahra Sadat Rezaeian

Position

PhD, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Hezar Jarib Ave. Isfahan University of Medical Sciences, Faculty of Rehabilitation Sciences

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 further 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