

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of high power laser in pain, stiffness and function of patients with patellofemoral pain syndrome (patellar chondromalacia)

Protocol summary

Summary

Patellofemoral pain syndrome is one of the most common musculoskeletal disorders in young adults. The pain existing in anterior knee or posterior patellar without other knee pathologies is called patellofemoral pain syndrome. In prospective studies the prevalence of this disease is reported to be 7% in active young adults and 15% in military staff. Although the main cause of this syndrome is unknown, some researchers believe that the pain can be attributed to some biomechanical, soft tissue or muscle abnormalities. This syndrome causes pain and functional disorder in the corresponding patients and if not treated well, it may result in chronic pain and/or weaknesses in quadriceps muscles. In the studies conducted so far, a variety of treatments including low power laser, orthoses, ultrasonography and rehabilitative exercises has been investigated while none of them has been proved to be significantly effective. Moreover, despite the growing use of high power lasers in alleviating musculoskeletal pains and its confirmed physiologic effects, studies investigating the effect of high power laser in pain management and function of patients with patellofemoral pain syndrome are very limited. Thus, the focus of this study is on analyzing the efficacy of high power laser in treatment of patients with patellar chondromalacia. To do so, a double blinded randomized clinical trial for the new treatment is designed in order to compare the efficacy of high power laser with the control group of isometric knee exercise, as the standard treatment for patellofemoral pain syndrome. In this study, 44 patients from PM&R clinic of Modarres and Shohada hospitals diagnosed with patellofemoral pain syndrome by clinical tests (Shrug test, Grind test, Perkins test) having the symptoms for three months with normal AP, lateral and patellar view knee xray are selected and divided into control and intervention groups, randomly. Five session of high

power laser in 2 weeks along with training isometric knee exercises are carried out on the intervention group. On the other hand, the control group undergoes 5 sessions of sham laser in 2 weeks accompanied by training isometric knee exercises. To evaluate and compare the two groups, the outcome of treatments will be measured by VAS score, WOMAC and kujala questionnaires. These measurements will be performed before intervention and 1 and 3 months after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100713442N19**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Physical Medicine and Rehabilitation Research Center of

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of high power laser in pain, stiffness and function of patients with patellofemoral pain syndrome (patellar chondromalacia)

Public title

Efficacy of high power laser in treatment of patients with patellar chondromalacia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 15 to 40 years; referring to the outpatient clinic of physical medicine and rehabilitation in year 1396; having positive exclusive patellofemoral syndrome maneuvers including Shrug test, Grind test and Perkins test (at least 2 of them being positive); symptoms duration of at least 3 months; having normal knee x-ray in 3 dimensions. Exclusion criteria: patients aged younger than 15 years or older than 40; with history of knee surgery; having a body mass index of 30 kg/cm² or more; any systemic diseases such as diabetes mellitus, immunodeficiency and collagen vascular disorders; history or presence of malignant cancer; history of recent knee trauma; any infection; pregnancy; breastfeeding; genu varum greater than 20 degrees; genu valgum greater than 20 degree; any knee deformity in knee x-ray; signs of knee osteoarthritis in knee x-ray

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Ave., Yaman St., Shahid Chamran highway

City

Tehran

Postal code

1985717443

Approval date

2017-06-13, 1396/03/23

Ethics committee reference number

IR.SBMU.MSP.REC.1396.197

Health conditions studied

1

Description of health condition studied

Patellar chondromalacia

ICD-10 code

M22.4

ICD-10 code description

Chondromalacia patellae

Primary outcomes

1

Description

Knee pain

Timepoint

Before, 1 month and 3 months after intervention

Method of measurement

Womac, VAS, Kujala questionnaires score

2

Description

Joint stiffness

Timepoint

Before, 1 month and 3 months after intervention

Method of measurement

Womac, Kujala questionnaires score

3

Description

Function

Timepoint

Before, 1 month and 3 months after intervention

Method of measurement

Womac, kujala questionnaires score

Secondary outcomes

empty

Intervention groups

1

Description

High power laser for 5 session in 2 weeks and multiangular isometric knee exercises for intervention group

Category

Rehabilitation

2

Description

Sham laser for 5 session in 2 weeks and multiangular isometric knee exercise in control group

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Maryam Sadat Rahimi

Street address

Tajrish square, Shohada Tajrish Hospital

City

Tehran

2

Recruitment center

Name of recruitment center

Shahid Modares Hospital

Full name of responsible person

Maryam Sadat Rahimi

Street address

shahid modares hospital, kaj square, saadat abad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Physical Medicina and Rehabilitation Department

Full name of responsible person

Seyyed Ahmad Raeissadat

Street address

Shahid Modarres Hospital, Kaj Square, Saadat abad,

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Physical Medicina and Rehabilitation Department

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Physical Medicine and Rehabilitation Departme

Full name of responsible person

Maryam Sadat Rahimi

Position

Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty