

# 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/cm<sup>2</sup> 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

#### Street address

Shahid Modares Hospital

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#### Postal code

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Science

#### Full name of responsible person

Seyyed Ahmad Raeissadat

#### Position

Professer of Physical Medicine and Rehabilitation Department

#### Other areas of specialty/work

#### Street address

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#### City

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**Person responsible for updating data**

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**Full name of responsible person**

Maryam Sadat Rahimi

**Position**

Resident of Physical Medicine and Rehabilitation

**Other areas of specialty/work**

**Street address**

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00

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**Web page address**

**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*