

# 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)

##### Phone

+98 13 3369 0099

##### Email address

kamranezzati@gums.ac.ir

##### 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<sup>2</sup>, 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

##### City

Rasht

##### Province

Guilan

##### Postal code

4193731943

##### Phone

+98 13 3332 2444

##### 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

##### City

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##### Province

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##### Postal code

9131293466

##### Phone

+98 13 3333 5821

##### Email

Research@gums.ac.ir

#### 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

##### Street address

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Research@gums.ac.ir

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

Guilan University of Medical Sciences

**Full name of responsible person**

Kamran Ezzati

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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

Guilan University of Medical Sciences

**Full name of responsible person**

Kamran Ezzati

**Position**

Assistant professor

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Ph.D.

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**Email**

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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**