# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## The Effect of High Power Laser Therapy on Pain and Physical Performance of Patient with Knee Osteoarthritis in comparison with conventional physical therapy.

## Protocol summary

**Summary**
The purpose of this study was to determine the effectiveness of High Power Laser Therapy (HPLT) in pain, range of motion, functional test, WOMAC questionnaire scores in patients with knee osteoarthritis compared with conventional physiotherapy. Sixty-two male and female patients aged between 50 to 75 years with primary knee osteoarthritis grade 2, 3 according Kellgren and Lawrence scale, assigned randomly into two groups; HPLT and conventional physiotherapy(CT) groups. After signing written consent, the subject will receive HPLT and a physical therapy program and a standard exercise therapy protocol which was same for both groups in multi center of sports medicine clinics. Patients at the beginning and end of the intervention and also three months (12 weeks) after the intervention will be assessed for primary outcomes included pain intensity, knee range of motion and secondary outcomes included functional tests and joint stiffness and activity of patient through WOMAC questionnaire.

## General information

**Acronym**
High Power Laser Therapy & Knee Osteoarthritis
**IRCT registration information**
IRCT registration number: **IRCT201701025486N5**
Registration date: **2017-06-19, 1396/03/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
**Registration date**
2017-06-19, 1396/03/29

**Registrant information**
**Name**
Azar Moezy
**Name of organization / entity**
Iran university of medical sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 6435 2446
**Email address**
moeziazr@sina.tums.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**
Iran University of Medical Sciences

**Expected recruitment start date**
2016-09-22, 1395/07/01
**Expected recruitment end date**
2018-02-20, 1396/12/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The Effect of High Power Laser Therapy on Pain and Physical Performance of Patient with Knee Osteoarthritis in comparison with conventional physical therapy.

**Public title**
The Effect of High Power Laser Therapy on Knee Osteoarthritis .
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: primary OA of the knee joint grade 2, 3 according Kellgren and Lawrence scale; age between 50-75; suffering from knee pain for at least six months

and with intensity 3 on the VAS scale in activities such as going up and down stairs, sitting and squat; no history of knee intra-articular injection in the past six months; no history of acute traumatic injuries; no history of previous surgery or injury in the knee joints and lower extremities; having a referral from a doctor; BMI equal to or less than 30; patient's consent to participate in the research; lack of neuromuscular disease; normal mental state; absence of bone implants; no history of new fractures; lack of cancerous tumors; no history of chronic disease such as epilepsy, migraine, acute hernia and generally any disease or condition that is known to affect the investigation; participate in sports programs and physical therapy in the recent three months. Exclusion criteria: unwillingness to participate in the study; uncompleted evaluation programs; uncompleted treatment programs; any damage in the knee joint during the study; using any other treatment except for the treatment prescribed in the research project.

**Age**

From **50 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **62**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization: Random allocation of the subjects was done by using a random number table and block random sampling; A: HPLT & B: CT (a block size of 4). Block 1: AABB Block 2: ABAB Block 3: BBAA Block 4: BABA Block 5: ABBA Block 6: BAAB In this study the patient, the therapist, as well as the assessor will be blinded to the study groups.The exact type of physical modalities will not be inserted in the consent form so the patient will be blind to treatment. In this study, the patients in HPLT group will be treated on even days and the other group patients will receive their treatment on odd days, to be unaware of treatment programs. The exact type of physical modalities will not be written in the consent form so the patients of each group will be blind to treatment. It should be noted that the exercise therapy protocol will be individually trained to the patient in the first day and an exercise therapy pamphlet with necessary pictures and explanations will be given to the patient to do exercises at home. In addition to the therapists who are responsible for doing therapeutic interventions are different in even and odd days, thus they will be blind to the intervention of the groups. Also, the assessor, a sports medicine assistant, who will evaluate the outcomes pre and post intervention in sports medicine clinic , will be blind to the patients in groups.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Sports Medicine Department, Hazrat Rasool Akram Hospital- Sattarkhan Ave, Niayesh St.

**City**

Tehran

**Postal code**

14455613131

**Approval date**

2016-10-18, 1395/07/27

**Ethics committee reference number**

IR.IUMS.REC 1395.9311225004

## Health conditions studied

### 1

**Description of health condition studied**

Primary knee osteoarthritis

**ICD-10 code**

M17.0 ,M17

**ICD-10 code description**

Gonarthrosis [arthrosis of knee]

## Primary outcomes

### 1

**Description**

Pain

**Timepoint**

pre / post intervention and three months after the intervention

**Method of measurement**

VAS pain scale

### 2

**Description**

Active knee range of motion

**Timepoint**

Pre / post intervention and three months after the intervention

**Method of measurement**

Goniometer

## Secondary outcomes

### 1

**Description**
Joint stiffness and functional state
**Timepoint**
Pre/Post and three months after Intervention
**Method of measurement**
Western Ontario and McMaster Universities Osteoarthritis Index

### 2

**Description**
Functional Activity
**Timepoint**
Pre/Post and three months after Intervention
**Method of measurement**
Timed Up & Go Test / Six-Minute Walk Test

## Intervention groups

### 1

**Description**
Intervention 1 (for HPLT group): The patients will be treated by high-power laser through PYSIOMED system (Belgium ) while the patient lying supine with the knee at 30 ° flexion three times a week for 10 sessions. The applicator (size:6 cm) will be placed vertically in contact with the joint and the knee in longitudinal and perpendicular direction will be scanned and irradiated with HPLT for 8 minutes with a power of 5 watts, duty cycle of 70%, frequency of 30 Hz and energy density 60 joules per square centimeter.
**Category**
Rehabilitation

### 2

**Description**
Intervention 2( for the control group): The patients will be treated by Combined BTL-4825 S Topline including High-frequency TENS( Duration: 50 microseconds, pulse rate :100 Hz with a maximum intensity tolerable for the patient , two electrodes on either side of the knee ,the treatment time : 20 minutes ) and Ultrasound (frequency: 1 MHz, mode: Continuous, probe size: 5 cm, treatment time: 8 minutes in the medial and lateral parts of knee in the supine position and with acoustic gel.) three times a week for 10 sessions.
**Category**
Rehabilitation

### 3

**Description**
Intervention 3- Common protocol for both groups: Exercise therapy: Also, both groups receive the same, standardized exercise therapy for knee osteoarthritis as follows: 1. Warm-up exercises: slow walking for 5 minutes, hamstring stretch and calf stretch. 2. Major exercises for knee osteoarthritis: SLR (Straight Leg Raise), quadriceps setting, pillow squeeze, heel raise, one leg balance, step ups, quadriceps strengthening exercise. Medication: In order to unify the participants' medications, all patients will be asked to stop taking their medications one week before the beginning the study and Acetaminophen will prescribe for them at a dose of two grams per day.
**Category**
Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Sports Medicine clinics in Iran University of Medical Sciences
**Full name of responsible person**
Dr Ahmad Nazari
**Street address**
Tehran
**City**
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Iran University of Medical Sciences
**Full name of responsible person**
Zhilla Chashmi
**Street address**
Iran University of Medical Sciences, Research Deputy, Central Headquarters (fifth floor),Hemat Highway between Sheikh Fadlallah and Chamran Expressway.
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Iran University of Medical Sciences
**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**
Iran University of Medical Sciences
**Full name of responsible person**
Dr Azar Moezy
**Position**
Associate Professor ,Sports Medicine.
**Other areas of specialty/work**
**Street address**
Sports Medicine Clinic, Hazrat Rasool Akram Hospital- Sattarkhan Ave, Niayesh St,
**City**
Tehran
**Postal code**
14455613131
**Phone**
+98 21 6435 2446
**Fax**
+98 21 6651 7309
**Email**
azarmoezy@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences.
**Full name of responsible person**
Dr Azar Moezy
**Position**
PhD Physiotherapy, Associate Professor.
**Other areas of specialty/work**
**Street address**
Sports Medicine Department, Hazrat Rasool Akram Hospital- Sattarkhan Ave, Niayesh St,
**City**
Tehran
**Postal code**
14455613131
**Phone**
+98 21 6435 2446
**Fax**
+98 21 6651 7309
**Email**
azarmoezy@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Dr Azar Moezy
**Position**
PhD Physiotherapy, Associate Professor.
**Other areas of specialty/work**
**Street address**
Sports Medicine Department, Hazrat Rasool Akram Hospital- Sattarkhan Ave, Niayesh St,
**City**
Tehran
**Postal code**
14455613131
**Phone**
+98 21 6435 2446
**Fax**
+98 21 6651 7309
**Email**
azarmoezy@yahoo.com
**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*