Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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.

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Tehran

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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
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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
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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

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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