Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the short-term Effects of Continues, Pulsed and Super pulsed High power Laser irradiation on Pain and Function in Patient with Knee Osteoarthritis

Protocol summary

Study aim

The main purpose of this study is comparing the short-term effects of continues, pulsed and super-pulsed high power laser irradiation on pain and function in the patients with knee osteoarthritis.

Design

A triple blinded randomized trial with parallel groups

Settings and conduct

52 patients (male and female) called to Shiraz Shahid Beheshti hospital Physiotherapy department will be enrolled in the study. These patients should have including criteria of this study with mild to moderate knee osteoarthritis. Also, they should sign a written informed consent for study participation. After that, they will be simply randomized to three groups (continuous, pulsed and super-pulsed high power laser with three routine exercises) through random number table. Demographic specifications of patients such as age, sex, and treatment group will be recorded in data collecting form. For blinding of study, none of the researcher or the evaluator won't know about grouping. Also, the Patients won't know which group they will be assigned or which treatment they will be offered. Each of patients will be evaluated for pain (through Visual Analog Scale "VAS" and Macgill Questionaire "MPQ"), edema in 3 locations (around the knee joint, 10 cm above and 10 cm belong that) using a measuring tape, Range of active knee extension, active and passive knee flexion and active and passive popliteal angle measuring by a goniometer before the first and immediately after the first and the fifth sessions. Also, the knee function of all patients will be evaluated before the first and immediately after the fifth session. All of the data will be recorded and, the results of them will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) Age ≥ 50 2) The osteoarthritic knee grade 2-3 based on radiographic diagnosis in the Kellegren and Lawrence grading of osteoarthritis by orthopedist physician. 3) The minimum score of 25 on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score. 4) Knee pain ≥ 4 on the visual analog scale (VAS) Exclusion Criteria: 1) History of physiotherapy or intra-articular injections during last 6 months. 2) Any history of knee surgery 3) History of fracture in knee 4) History of tearing of tendons, ligaments, and menisci in knee joint 5) Central or peripheral neuropathy 6) Rheumatoid Arthritis 7) Malignancy in knee joint 8) Psychologic problems 9) Metabolic disease such as Diabetes, Thyroid, and Kidney problems 10) Infective disease 11) Ankylosis 12) Sever Synovitis 13) Sever valgus or Varus deformity 14) Incomplete treatment for any reasons 15) Osteoarthritic knee of grade 1,4 based on radiographic diagnosis in the Kellegren and Lawrence grading of osteoarthritis

Intervention groups

1) Continuous-high power laser group: Five sessions, on consecutive days, with continuous high power laser accompanied by 3 routine exercise for knee osteoarthritis. In this group, according to the knee-arthrosis protocol of the device (from continuous source), the laser will be irradiated on 8 points of the knee joint with the total energy dose of 251.2 J during 10 min. 2) Pulsed-high power laser group: Five sessions, on consecutive days, with pulsed-high power laser accompanied by 3 routine exercise for knee osteoarthritis. In this group, according to the Analgesic protocol of the device (from pulsed source), the laser will be irradiated on 8 points of the knee joint with the total energy dose of 199 J during 10 min. 3) Super-pulsed-high power laser group: Five sessions, on consecutive days, with super-pulsed-high power laser accompanied by 3 routine exercise for knee osteoarthritis. In this group, according to the Knee-arthrosis protocol of the device (from super-pulsed source), the laser will be irradiated on 8 points of the knee joint with the total energy dose of 565 J during 10 min.

Main outcome variables

1) Pain Score 2) Knee Function Score 3) Edema of the knee joint, 10 cm above and 10 cm belong that. 4) Active Knee Extension ROM 5) Active Knee Flexion ROM 6) Passive Knee Flexion ROM 7) Active Popliteal Angle 8) Passive Popliteal Angle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170131032338N3**
Registration date: **2018-01-29, 1396/11/09**
Registration timing: **prospective**

Last update: **2018-01-29, 1396/11/09**
Update count: **0**

Registration date

2018-01-29, 1396/11/09

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 5132

Email address

n-rahimpour@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-31, 1396/11/11

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the short-term Effects of Continues, Pulsed and Super pulsed High power Laser irradiation on Pain and Function in Patient with Knee Osteoarthritis

Public title

Effect of High power Laser in Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≥ 50 Osteoarthritic knee of grade 2-3 based on radiographic diagnosis in the Kellegren and Lawrence grading of osteoarthritis by orthopedist physician. The minimum score of 25 on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score Knee pain ≥ 4 on the visual analog scale (VAS)

Exclusion criteria:

History of physiotherapy and/or intra-articular injections during last 6 months. Any history of knee surgery History of fracture in knee History of tearing of tendons, ligaments and menisci in knee joint Central or peripheral neuropathy Romatoid Arthritis Malignancy in knee joint Psychologic problems Metabolic disease such as Diabetes, Thyroid, and Kidney problems Infective disease Ankylosis Sever Synovitis Sever valgus or Varus deformity Incomplete treatment for any reasons Osteoarthritic knee of grade 1,4 based on radiographic diagnosis in the Kellegren and Lawrence grading of osteoarthritis

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**
More than 1 sample in each individual
Number of samples in each individual: **52**
Each of the 52 patients who have unilateral knee osteoarthritis with low or moderate pain referred to Shiraz physiotherapy clinics will be a sample for the study. In patients with bilateral knee osteoarthritis, the more painful joint will be cured.
Actual sample size reached: **49**
More than 1 sample in each individual
Actual sample size in each individual: **49**
Each of patients is evaluated for pain (with 2 scales), edema in 3 locations (around knee joint, 10 cm above and 10 cm belong that), Range of active extension, active and passive flexion, active and passive popliteal angle before the first session, immediately after that and immediately after the fifth session. Also, knee function of all patients is evaluated before the first and immediately after the fifth session.

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are simply randomized to three experimental groups (Pulsed and Super pulsed High power Laser) through random number table; received a special code and are treated with own group treatment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

treatments are done by the researcher and; evaluations are done by another evaluator; none of them doesn't understand about patients grouping. moreover, analysis

of data is done by a statistician who doesn't know about grouping. Also, the patients don't know about their group and other groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Official Building, Medicine Faculty of Tehran University of Medical Sciences, Poorsina Ave., 16 Azar Ave., Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2017-08-06, 1396/05/15

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3049

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis

ICD-10 code
M17

ICD-10 code description
Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description
Pain Score

Timepoint
Evaluating the pain score before the first session and immediately after the first and the fifth treatment sessions.

Method of measurement
(Visual Analog Scale) VAS and (MCQ) (Mc-gill Questionnaire)

2

Description
Knee Function Score

Timepoint
Evaluating the knee function score before the first and immediately after the fifth treatment sessions.

Method of measurement
WOMAC Questionnaire

3

Description
Edema of knee joint, 10 cm above and 10 cm belong that.

Timepoint
Evaluating the knee joint edema before the first session and immediately after the first and the fifth treatment sessions.

Method of measurement
Measuring tape

4

Description
Active Knee Extension ROM

Timepoint
Evaluating Active Knee Extension ROM before the first session and immediately after the first and the fifth treatment sessions.

Method of measurement
Goniometer

5

Description
Active Knee Flexion ROM

Timepoint
Evaluating Active Knee Flexion ROM before the first session and immediately after the first and the fifth treatment sessions.

Method of measurement
Goniometer

6

Description
Passive Knee Flexion ROM

Timepoint
Evaluating Passive Knee Flexion ROM before the first session and immediately after the first and the fifth treatment sessions.

Method of measurement
Goniometer

7

Description
Measuring Active Popliteal Angle

Timepoint
Measuring Active Popliteal Angle before the first session and immediately after the first and the fifth treatment sessions.

Method of measurement

Goniometer

8

Description
Measuring Passive Popliteal Angle
Timepoint
Measuring Passive Popliteal Angle before the first session and immediately after the first and the fifth treatment sessions.
Method of measurement
Goniometer

Secondary outcomes

empty

Intervention groups

1

Description
The first group: 5 treatment sessions with continuous high power laser according to the Knee-arthrosis protocol of the Lumix 3 ultra device produced by Fisioline, Italy on the 8 points of the knee joint during 10 minutes with the total energy dose of 251.2 J accompanied by 3 routine exercise for knee osteoarthritis include: 1- Quadriceps setting, 2- Straight Leg Raising (SLR) and 3- Hamstring muscle stretching exercises.
Category
Rehabilitation

2

Description
The second group: 5 treatment sessions with pulsed high power laser according to the Analgesic protocol of the Lumix 3 ultra device produced by Fisioline, Italy on the 8 points of the knee joint during 10 minutes with the total energy dose of 199 J accompanied by 3 routine exercise for knee osteoarthritis include: 1- Quadriceps setting, 2- Straight Leg Raising (SLR) and 3- Hamstring muscle stretching exercises.
Category
Rehabilitation

3

Description
The third group: 5 treatment sessions with super-pulsed high power laser according to the Knee-arthrosis protocol of the Lumix 3 ultra device produced by Fisioline, Italy on the 8 points of the knee joint during 10 minutes with the total energy dose of 565 J accompanied by 3 routine exercise for knee osteoarthritis include: 1- Quadriceps setting, 2- Straight Leg Raising (SLR) and 3- Hamstring muscle stretching exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Dr Beheshti Hospital
Full name of responsible person
Nadia Rahimpour
Street address
Shahid Dr Beheshti Hospital, Valiasr Squar
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7144984765
Phone
+98 71 3224 1161
Email
rahimpourpt@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of medical sciences, Research and Technology Dept.
Full name of responsible person
Dr. Sahraeian Mohammad Ali
Street address
Keshavarz Blvd, Ghods St., Central Organization of the Tehran University of medical sciences, 6th floor, Research and Technology Dept.
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Province
Tehran
Postal code
1417653761
Phone
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Email
rahimpourpt@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of medical sciences, Research and Technology Dept.
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

Tehran University of Medical Sciences

Full name of responsible person

Rahimpour Nadia

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Full name of responsible person

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Position

Student

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Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the results of the analyzed personal data such as primary outcomes will be shared after making them unknown.

When the data will become available and for how long

Start of access from 2020

To whom data/document is available

The data are accessible only for researchers of the universities and Scientific institues

Under which criteria data/document could be used

The data will be shared only for helping knowledge of researchers. Any statistical and analytic use of data are forbidden.

From where data/document is obtainable

Nadia Rahimpour Postal Address: No. 267, 8/1 Ave., 1

Ave., Jomhouri Blvd., Shiraz, Iran. E mail: rahimpourpt@gmail.com Tel: 0098 71 32286628 Mobile: 0098 9177164101

What processes are involved for a request to access data/document

After receiving request for data cashing requester identity and reason of request will be considered. Then the data will be sent maximally during 2 months for requester.

Comments