

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of high power laser therapy vs low level laser therapy on the range of motion , functional ability and quadriceps architecture in patients with knee osteoarthritis : A double blinded randomized clinical trial

Protocol summary

Study aim

The effects of high power laser therapy vs low level laser therapy on the range of motion , functional ability and quadriceps architecture in patient with knee osteoarthritis

Design

A randomized, controlled, blinded, clinical trial with a parallel group design of 75 patients

Settings and conduct

The effects of laser therapy in patients with osteoarthritis. All procedures will be performed in Poursina Hospital, Guilan University of Medical Sciences. The patients will be in 3 groups double blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 40-70 yrs; Osteoarthritis grade 1 or 2. non-inclusion criteria: Rheumatoid arthritis; complete tear anterior cruciate ligament or menisci; Hyalgan or corticosteroids injection in last 6 months; Grade 3 and 4 osteoarthritis

Intervention groups

1-Control group: 1) The Infrared bulb is positioned at a distance of 50 cm from the knee. 2- Transcutaneous electrical nerve stimulation(TENS) 3- Ultrasound: Intensity 1 w/cm², continuous on both sides of the knee about 4 minutes 4- Exercise for strengthening muscle should include 10 exercises up to 4 weeks. 2- Low level laser therapy Treatments in control group and low level laser therapy 3- High power laser therapy Treatments in control group and high power laser therapy

Main outcome variables

Fiber angle and length; volume and thickness of vastus medialis oblique and vastus lateralis muscles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N5**

Registration date: **2019-04-21, 1398/02/01**

Registration timing: **prospective**

Last update: **2019-04-21, 1398/02/01**

Update count: **0**

Registration date

2019-04-21, 1398/02/01

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

2019-05-10, 1398/02/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of high power laser therapy vs low level laser therapy on the range of motion , functional ability and quadriceps architecture in patients with knee osteoarthritis : A double blinded randomized clinical trial

Public title

The effects of laser therapy on symptoms of patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Radiologic signs of grade 1 and 2 Kellgren-Lawrence: Decrease of joint space and existence of osteophytes
Visual analogue scale (VAS) score of 3 or more
Body mass index < 30

Exclusion criteria:

The patients with rheumatoid arthritis; malignancy; knee surgery; fracture; complete tear anterior cruciate ligament or menisci; athletics; neuropathy, genu valgum or varum more than 20 degree; hyalgan or corticosteroids injection in last 6 months. Physiotherapy in last month grade 3 and 4 Kellgren-Lawrence in radiologic examination Bilateral knee pain or local infection Acute bursitis or tendinitis of the knee Referral pain from lumbar or hip to knee.

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The grouping method will be stratified permuted block randomization . Equal number of patients from 3 groups will be matched based on age, Body mass index, dominant side and affected knee. So, 3 blocks of 10 people for 3 groups will be allocated. A software engineer at the ward will perform this method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The examiner and statistical analyzer won't know anything about the kind of treatment.

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

2019-01-10, 1397/10/20

Ethics committee reference number

IR.GUMS.REC.1397.366

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, After ten sessions treatments, one month follow-up

Method of measurement

Visual Analogue Scale

2

Description

Fiber angle; volume and thickness of vastus medialis oblique

Timepoint

Before intervention, After ten sessions treatments, one month follow-up

Method of measurement

Using ultrasonography

3

Description

Fiber angle and length; volume and thickness of vastus lateralis

Timepoint

Before intervention, After ten sessions treatments, one month follow-up

Method of measurement

Using ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

1-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 individuals. The patient will feel mild heat. 2- Treatment with transcutaneous electrical nerve stimulation(TENS) type brief for 20 minutes. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations about 20 minutes. 3- Ultrasound: Intensity 1 w/cm2, continuous on both sides of the knee about 4 minutes 4- Exercise for strengthening muscle should include 10 exercises up to 4 weeks.

Category

Rehabilitation

2

Description

2- Low level laser therapy: All interventions in control group with low level laser therapy: Laser therapy (laser med, Carci, brazil) with 808 nm wavelength, 12 joules, 50 mW on 12 points of the knee. Each point treatment time will be 91 seconds.

Category

Rehabilitation

3

Description

3- High power laser therapy: All interventions in control group with high power laser therapy: Laser therapy (High power laser, pagani, Italy) with 808 nm wavelength, 12 joules, 1.6W on all areas of the . Treatment time will be 150 seconds.

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

Kamranezzati@gums.ac.ir

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

Rasht

Province

Guilan

Postal code

9131293466

Phone

+98 13 3333 5821

Email

Kamranezzati@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
Deputy of Research, Opposite to Azodi Stadium,
Namjoo St, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 2639
Email
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
Street address
Central Office of Guilan University of Medical
Sciences, Parastar St., Rasht, I.R. Iran
City
Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3369 0099
Email
kamranezzati@gums.ac.ir

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
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Central Office of Guilan University of Medical
Sciences, Parastar St., Rasht, I.R. Iran
City
Rasht
Province
Guilan
Postal code
۴۱۹۳۷۱۳۱۹۴
Phone
+98 13 3369 0099
Email
kamranezzati@gums.ac.ir

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