

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The Comparison between effect of high intensity and low intensity laser therapy on pain, disability and joint effusion in patients with chronic knee osteoarthritis grade 1,2: A Randomized Clinical Trial

Protocol summary

Study aim

The Comparison between effect of high intensity and low intensity laser therapy on pain, disability and joint effusion in patients with chronic knee osteoarthritis grade 1,2

Design

A randomized, controlled, blinded, clinical trial with a parallel group design of 71 patients

Settings and conduct

The effects of laser therapy in patients with osteoarthritis. All procedures will be performed in khatam hospital, zahedan university of medical sciences. The patients will be in 3 groups double blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 40-60 yrs; Osteoarthritis grade 1 or 2. non-iclusion 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- Exercise for strengthening,stretching,rane of motion muscle should include 6 exercises . 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

Supra patella effusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N8**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

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Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-08, 1398/04/17

Expected recruitment end date

2019-10-09, 1398/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison between effect of high intensity and low intensity laser therapy on pain, disability and joint effusion in patients with chronic knee osteoarthritis

grade 1,2: A 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
Body mass index<40

Exclusion criteria:

The patients with rheumatoid arthritis; malignancy; knee surgery; fracture; complete tear anterior cruciate ligament or menisci; athletics; neuropathy, hyalgan or corticosteroids injection in last 6 months. Physiotherapy in last month Grade 3 and 4 Kellgren-Lawrence in radiologic examination Local infection Referral pain from lumbar or hip to knee

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **71**

More than 1 sample in each individual

Number of samples in each individual: **2**

One participant may have osteoarthritis in Both knees, and both knees are used in this study as sample.

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. 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)

Single blinded

Blinding description

Although routine physical therapy will be performed for all patients, they won't know anything about laser therapy and the kind of it. So, the patients are blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of zahedan University of Medical Sciences

Street address

daneshgah blvd, dr hessabi square

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.ZAUMS.REC.1398.140

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary 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

Area of supra patella effusion

Timepoint

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

Method of measurement

Using ultrasonography

3

Description

Thickness of supra patella effusion

Timepoint

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

Method of measurement

Using ultrasonography

4

Description

Disability

Timepoint

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

Method of measurement

WOMAC questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 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- Exercise for strengthening,range of motion, stretching muscle should include 6 exercises.

Category

Rehabilitation

2

Description

Int Low level laser therapy: All interventions in control group with low level laser therapy: Laser therapy (laser med, Carci, brazil) with 905 nm wavelength, 12 joules, 50 mW on 10 points of the knee. Each point treatment time will be 912 seconds.

Category

Rehabilitation

3

Description

Intervention group: High power laser therapy: All interventions in control group with high power laser therapy: Laser therapy (High power laser,New Age , Italy) with 905 nm wavelength, 12 joules, 1.6W on all areas of the . Treatment time will be 300 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam hospital

Full name of responsible person

Fatemeh Ghiasi

Street address

Physiotherapy section, khatam hospital,jaam jam boulevard, Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Anahita Hasannejad
Position
student
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Person responsible for updating data

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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

Adress: 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 researche

Comments