# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Sep 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 hispital, 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**
Kamran Ezzati

**Name of organization / entity**
Guilan University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 13 3369 0099

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kamranezzati@gums.ac.ir

**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**
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public@zaums.ac.ir
**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

**Latest degree**
Bachelor

**Other areas of specialty/work**
Physiotherapy

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## Person responsible for scientific inquiries

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hasan namvar

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educator

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**
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**Position**
Assistant Professor

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**Other areas of specialty/work**
Physiotherapy

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1319441937

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Ez_kamran@yahoo.com

**Web page address**

## 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 publicating 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**