

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

effect of Augmented High Intensity Laser Therapy (HILT) to Electrical Stimulation (NMES) and Exercise Therapy on Muscle Strength, Pain and Function in Patients with Knee Osteoarthritis Grade II and III: a randomized controlled trial

Protocol summary

Study aim

Investigation the effects of augmented high intensity LASER therapy with electrical stimulation and exercise therapy on muscle strength and pain and function in patients with knee osteoarthritis grade II and III : A Randomized Clinical Trial

Design

Clinical trial with control group, Two arm parallel group, double blind with blinded outcome evaluator and participants, simple randomised

Settings and conduct

Participants after having inclusion criteria for entry to test randomly simple in two groups control group: Placebo high intensity LASER with neuromuscular electrical stimulation and exercise therapy Treatment group: High intensity LASER with neuromuscular electrical stimulation and exercise therapy Ten treatment sessions were done for participants. Assessment of participants done before and after treatment, session 10, A month and a half after treatment. Assessment of pain performed with visual analog scale, strength of quadriceps muscle with manual dynamometer and function with Western Ontario and McMaster Universities Arthritis Index. This is a double-blind study with blinded outcome evaluator and participants. All stages of study were conducted at Ahwaz Jundishapour University of Medical Sciences.

Participants/Inclusion and exclusion criteria

inclusion criteria: Radiographic evidence of knee and knee osteoarthritis, Knee pain for at least three months, physiotherapy and injection within the last six months. no pacemaker, cardiovascular disease, knee arthroplasty, tumor and deep vein thrombosis. Exclusion criteria: No willing the samples to continue the treatment process

Intervention groups

control group: Placebo high intensity LASER with neuromuscular electrical stimulation and exercise therapy Treatment group: High intensity LASER with neuromuscular electrical stimulation and exercise therapy

Main outcome variables

Pain Strength of Quadriceps muscle function

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20181024041442N1**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

Registrant information

Name

Shahin Goharpay

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3101

Email address

goharpay-sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effect of Augmented High Intensity Laser Therapy (HILT) to Electrical Stimulation (NMES) and Exercise Therapy on Muscle Strength, Pain and Function in Patients with Knee Osteoarthritis Grade II and III: a randomized controlled trial

Public title

effect of high intensity laser therapy on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Radiographic evidence of knee osteoarthritis grade II and III according to the Kellgren-Lawrence classification and based on American College of Rheumatology (ACR) criteria knee pain for at least 3 months. without application of injection or physiotherapy during the last six months

Exclusion criteria:

Not willing the samples to continue the treatment process

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomized Individual Use the random numbers table People first enter each number next members were selected with 5 spacing

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants did not know the presence of the control group. Also, they did not know what treatment group they were supposed to be. Assessing the outcome without knowing the types of groups and types of treatments evaluated the participants before and after treatment.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Department of Physical Therapy, School of Rehabilitation Sciences, Ahwaz Jundishapur University of Medical Sciences, Ahwaz, Iran

City

Ahwaz

Province

Khouzestan

Postal code

61357-33133'

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.AJUMS.REC.1397.267

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis Grade II and III

ICD-10 code

M15.9

ICD-10 code description

Generalized Osteoarthritis NOS

Primary outcomes**1****Description**

pain

Timepoint

before treatment, session10, A month and a half after treatment

Method of measurement

The visual Analog scale of pain. score is from 0 to 100 mm. 100 max pain and 0 painless state.

2**Description**

strength of quadriceps

Timepoint

before treatment, session10, A month and a half after

treatment

Method of measurement

manual dynamometer

Secondary outcomes

1

Description

function

Timepoint

before treatment, session10, A month and a half after treatment

Method of measurement

Western Ontario and McMaster Universities Arthritis Index

Intervention groups

1

Description

Intervention group includes high intensity laser with neromuscular electrical simulator and exercise therapy

Category

Treatment - Devices

2

Description

Control group includes neromuscular electrical simulator and exercise therapy

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvar Jondishapour University of Medical Sciences

Full name of responsible person

Dr. Shahin Goharpey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badvi

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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

Ahwaz 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

Ahwaz University of Medical Sciences

Full name of responsible person

Dr Shahin Goharpey

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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